A STRONG, TRANSPARENT AND PROACTIVE PHARMACOVIGILANCE SYSTEM

BEUC response to the public consultation on the legislative proposal on Pharmacovigilance

Contact: Ilaria Passarani – health@beuc.eu
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BEUC, the European Consumers' Organisation
36 avenue de Tervueren, 1040 Bruxelles - +32 2 743 15 90
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Summary

A strong, transparent and proactive pharmacovigilance system is vital to ensure consumer safety in relation to the use of medicines.
BEUC welcomes the European Commission initiative to update the existing legislation but urges the text submitted for public consultation[1] to be improved. In particular we ask for:

- Consumers to be enabled to report adverse reactions directly to the national authority for all medicines, including those intensively monitored, and not to the marketing authorisation holder;
- Clear and transparent safety information, namely a pictogram to help consumer distinguish immediately intensively monitored drugs, Patient Safety Update Reports (PSURs) and medicines consumption data to be made public, Eudravigilance to be regularly updated and easily accessible by consumers;
- A harmonized, transparent and centralized system both for marketing authorization procedures and for medicines safety issues;
- The simplification of procedures to guarantee high quality standards and to be balanced with strict rules in case of non-compliance;
- The principle of therapeutic efficacy and added value to be considered essential criteria for the marketing authorization ensuring consumers access to safe, effective and technologically advanced medicines;
- Transparent and non-promotional post authorisation safety studies;
- Independent research and safety studies for a more proactive pharmacovigilance system;
- Public education campaigns to raise awareness about the importance of side effects reporting;
- Competence on pharmacovigilance and on medicines to be moved from DG ENTERPRISE to DG SANCO.

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This is the BEUC response to the European Commission public consultation on a "Strategy to better protect Public health by strengthening and rationalising EU Pharmacovigilance"[1].

A strong, transparent and proactive pharmacovigilance system is vital to ensure consumer safety in relation to the use of medicines. BEUC welcomes the European Commission initiative to update the existing legislation which needs to be changed to strengthen the EU pharmacovigilance system and to attain a higher level of health protection. Even though the proposal presents some progress, it is a long way far from our expectations and needs to be improved.

1. Consumer reporting of adverse reactions directly to the national authority

The importance of consumer reporting

Consumers are key stakeholders in relation to pharmacovigilance and can actively contribute through an integrated and efficient reporting system.
Direct reporting is an essential tool to empower consumers and to improve their involvement in the management of their own health.
With direct reporting, adverse drugs reactions (hereafter ADRs) will be detected earlier, more ADRs would be reported (e.g. on Over the Counter medicines) and health professionals will not act as a filter.
The evidence[2] indicates that patient reports which are unfiltered by professional interpretation can bring a new contribution to understanding ADRs, particularly those that have not previously been known. In Sweden, Kilen, a patients reporting system run by a consumer group, has conducted a study comparing professional and patient reports of ADRs for the SSRI antidepressant, sertraline, and a summary analysis on its website shows substantial differences between patient and professional reports: "Patients' descriptions of suspected ADRs to SSRIs identified some symptoms which health professionals were unable to describe correctly in their ADR reports. [3]
In addition patients may use vocabulary which is enlightening in understanding adverse drug reactions as the use of medical terminology by doctors sometimes leads to less detail and meaning. For example, when patients report "electric shock sensations" in the withdrawal of antidepressants, this has been "tranlated" as "paraesthesia", which communicates little of the disabling impact of withdrawal symptoms on users.

[1] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance_acs/docs/public-consultation_12-2007.pdf
[2] Report from the CHMP Pharmacovigilance Working Party (PhVWP) on Direct Reporting of adverse reactions by patients, 22 January 2008.
[3] Patient reporting of suspected adverse drug reactions "A review of published literature and international experience", A. Blenkinsopp et al, British Journal of Clinical Pharmacology 2006.

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The experience of Test-Achats

Our Belgian member, Test-Achats, started in November 2006 an initiative on patients reporting in collaboration with the Belgian Agency of Medicines (FAGG). The form used is available online in French at www.contactmedicaments.be and in Dutch at www.meldpuntgeneesmiddelen.be) but everybody can also receive a paper form calling the contact centre of Test-Achats.
Test-Achats experts' team (pharmacists and medical doctors) sends the report to the pharmacovigilance department of the medicines agency. Within a month the agency sends the evaluation back to Test-Achats who provides a feedback to the consumer. From November 2006 to December 2007, 184 ADRs were reported. Test-Achats also registered 56 reports of other drug related problems and received 31 questions regarding price and reimbursement and 15 regarding the patient information leaflet. Most of the reports were on drugs used to treat cardiovascular diseases, diseases affecting the central nervous system and gastrointestinal diseases. The most frequently reported ADRs were muscular pain (9), nausea (9), dizziness (9), sleeping disorders (8), allergic reaction (7) and increase in weight (6). The most ADRs are reported from the following active substances: simvastatine (10), rosuvastatine (10), omeprazole (6), venlafaxine (5).This initiative revealed to be very successful: overall 240 reports were collected; consumers showed to report correctly and in a detailed manner and the Agency of medicines used the reports. This resulted in an increased consumer involvement on pharmacovigilance and a better insight in the drug related problems for consumers; in other words a better pharmacovigilance system.

The experience of Altrocosumo

Our Italian member, Altroconsumo, launched in June 2006 on its web site the initiative "Questa la racconto" (I tell you my story) to collect consumers experiences of adverse reactions following the use of some specific medicines. At the beginning they did it for two creams used to treat eczema and then they expanded it to coxib and to glitazones used to treat diabetes. In one year, they received 230 reports. The reports were sent to AIFA, the Italian medicines agency. This initiative showed that consumers' reports are essential not only to know more about adverse drugs reactions but also to know when the medicines are not used appropriately. For example, in the case of the two creams for eczema, Altroconsumo showed that they were prescribed for age not authorised, as first option treatment and not as second option treatment as required from the competent authorities and for longer period of time than suggested.

At the moment consumers are allowed to report directly ADRs via the national Medicines agency websites in the Netherlands, in Denmark, in Italy, in France and in the UK but these initiative are not enough promoted. In the Netherlands there is also a consumers' organization – run system, Meldpuntmedicijnen, like Kilen in Sweden.

Consumer reporting in the legislative proposal

On the basis of these positive experiences BEUC welcomes the introduction of a system that enables consumers direct reporting of side effects but we consider unacceptable that, for intensively monitored drug, reports go to the marketing authorization holders as foreseen in art. 59 of the proposal.
We do not understand the rationale behind this provision and we strongly believe that, for all medicines, reports should go directly to the national authority.

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2. Clear and transparent safety information

- *A pictogram to help consumer distinguish immediately intensively monitored drugs*

We welcome the provision of the proposal regarding the introduction of safety information on the package leaflet and the warning for medicines under intensive surveillance as we believe that the patient information leaflets need to be designed to convey potential adverse reactions more clearly, so that the relative likelihood of these occurring is included and people know what to do if they do occur.

The introduction of the adverse reaction form as well as a European list of medicines under intensive monitoring are good step forwards to empower consumers to report their side effects and to increase their confidence in the safety of medicines.

BEUC proposes to go further by adding a pictogram - like the black triangle scheme used in the UK - to the wording "This medicinal product is under intensive monitoring. All adverse reactions should be reported". This would help consumer to identify new drugs under intensive surveillance and would increase consumer awareness to report any adverse reaction that appears with these drugs.

- *Patient safety update reports and medicines consumption data to be made public*

Patient safety update reports (PSURs) are a central tool in pharmacovigilance and, from a consumer perspective, they may have more weight if made public, fully respecting privacy protection.
The data relevant to the benefits and risks of the medicine and the data relating to the volume of sales and the volume of prescriptions should also be regularly updated and made public.

- *Eudravigilance*

We consider essential to have one single reporting point irrespective of the licensing route and we support the use of Eudravigilance that should be regularly updated and accessible also to consumers and health care professionals.

3. Centralised procedures for marketing authorisations and medicines' safety issues by EMEA

BEUC supports the establishment of a Pharmacovigilance Committee within the EMEA to replace the existing Pharmacovigilance working party and welcomes that the outcomes of the Committee will be binding Commission decisions. This will bring coherence in the implementation of safety actions in all Member States, ensuring consumers the same level of protection across Europe.
We are also glad that patients and consumers will be represented and we hope for a close collaboration between the Committee and the EMEA Patients and Consumers Working Party.

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A harmonised, transparent and centralised system is essential not only with regard to the safety issues but also for the marketing authorisation procedures.
As foreseen by regulation 726/2004, as of 20 May 2008 the centralised procedure will be obligatory for 7 categories of medicines (AIDS, cancer, viral infections, autoimmune disease, rare diseases, diabetes and neurodegenerative disorders) and we ask it to be extended to all medicines in the very near future.

4. Pharmacovigilance Master File to be submitted for the marketing authorisation

BEUC understands the need to simplify and rationalize the administrative procedures but the simplification should not affect the quality standards and should not jeopardize consumer safety. In this respect we support the creation of an automatic pharmacovigilance referral but we consider the provisions regarding the Pharmacovigilance System Master file (see articles 8, 23, 101l and 111) insufficient to ensure a high level of public health and consumer protection.
To make certain that medicines are effectively monitored as soon as they enter in the market, the pharmaceutical companies should develop and present a detailed description – and not only a summary - of the pharmacovigilance system to the authorities together with the application for the marketing authorisation.

5. Strict rules in case of non-compliance

The proposed changes to existing legislation are all oriented towards the reduction of burocratic burdens and costs for the industry in order to “have better compliance”. Pharmaceutical companies will benefit from “light and fast procedures», a reduction in costs and a “faster return on investment».
These benefits and the reduction in regulatory scrutiny leave now no excuses for any situation of non compliance and need to be balanced by stricter rules and stronger sanctions. In order to achieve this, art. 101o should be fostered and explicitly foresee penalties including the suspension of the marketing authorization.

6. Therapeutic efficacy and added value essential criteria for the marketing authorization

In articles 26, 116 and 117 the Commission proposes to exclude the principle of efficacy from the criteria used to decide for the refusal, suspension, withdrawal and variation of the marketing authorisation. We consider this an unfortunate step back compared to the text adopted in 2004: newly approved medicines do not necessarily equal better medicines - despite their often higher prices - and it is essential to know their efficacy in order to balance the benefits they might bring with the risks to expose patients to new adverse reactions.
BEUC strongly believe that newly approved drugs should prove not only their efficacy but also their added value and should undergo a comparative assessment not with a placebo but with the best available treatment.

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7. Non-promotional post-authorization safety studies

We are glad that requirements for post-authorization studies have been included as a condition of the marketing authorization and that the Commission acknowledged that post authorization safety studies "are often of poor quality and frequently promotional" but the provisions of art. 101 (g and h) should be much stricter to ensure full transparency. In particular, we think that the request to conduct a post-authorization study, as well as the explanation of the marketing authorization holder and the final decision of the competent authority should be disclosed to the public. In addition, the results of the study should always be made public via the EMEA web site and should not be submitted to the agreement of the marketing authorisation holder. Finally we believe that also the Pharmacovigilance Committee should be entitled to ask the marketing authorisation holder to conduct a post-authorisation safety study.

8. Independent research and safety studies for a proactive pharmacovigilance system

In order to focus on the potential long-term effects of new medicines and to supplement companies' post-authorization safety studies and spontaneous reporting from consumers and healthcare professionals, the EMEA and the Member States should carry out additional independent research that follows a selected group of patients using specific medicines after they have been granted market authorization.

It is important that independent research is carried out inside and outside the agencies as part of the pharmacovigilance system and involves academia, centers of excellence and regional surveillance centers.
The EU should support - for example through call for tenders or the VII Research Framework Programme - high quality independent research not only on pharmacovigilance but also on methodologies, pharmacoepidemiology and safety studies according to public health needs.

9. Raise awareness about the importance of side effect reporting

The provisions of the directive should be complemented by public information and education campaigns, through the EMEA and national agency websites, health centers, consumers and patients' organisations, etc., on the importance of side effects reporting and it should be a key part of training for health professionals.

10. Competence on pharmacovigilance to be moved from DG ENTERPRISE to DG SANCO

BEUC strongly believes that the prime objective of any pharmaceutical policies, both at national and EU level, should be meeting patient needs. Decision makers' first priority should be to secure health policy objectives including protecting public health, ensure access to safe, effective, affordable and appropriate medicines, improve quality of care, and ensure equity and efficiency.

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To achieve this, to ensure that medicines are considered exclusively as a public health issue and not seen from an industrial perspective,[4] and to ensure that internal market arguments and "return on investments" do not override the consumers' right to safe, effective and technologically advanced medicines, we believe that the Directorate for Health and Consumer Protection (DGSANCO) and not the Directorate General for Enterprise and Industry should be responsible for pharmacovigilance and more generally for pharmaceutical policies.

END

[4] "Put health first", BEUC, October 2007.

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