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Commission Public Consultation: As Assessment of the Community System of Pharmacovigilance.

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Type of Stakeholder: Consumer organisation

Organisation: Danish Consumer Council

Comments:

It is mentioned as one of the general aspects in the report, that in the light of recent safety crises, it has been obvious that especially independent safety studies are very important to identify safety issues. The Danish Consumer Council fully supports this point of view. The Council would at the same time like to draw the attention to the fact, that the national authorities are closely linked to the pharmaceutical industry through financially connections between the authorities and the industry. It is important that independent research is carried out, inside or outside the agencies as a part of the pharmacovigilance system. This could support pharmacovigilance strongly, but only if it is carried out indepentdently from the industry.

It is not very very obvious from the report, that patients and consumers are stakeholders in relation to pharmacovigilance and also central ressource persons, who can contribute to pharmacovigilance through a reporting system. Reporting systems are built up in a few countries, and experience has to be collected from these initiatives so that the good experience and initiatives with influence to pharmacovigilance could be found and shared between the member countries. The reporting system gives patients a chance to be heared about their experiences with medicine and to bring their share to pharmacovigilance.

The report mentions PSUR as a central tool in phamacovigilance, but from a consumer perspective the PSUR could have even more weight in pharmacovigilance, if they were also made public with the result that others than industry and agencies could have access to them and the assessments that are included in the PSUR. This could be an initiative that would also bring more transparency and openness into the pharmacovigilance system. When the PSUR is made public it should of course happen with respect to the privacy of the patients involved.

The Council would also like to propose a nem labelling system. New medicines on the market could be labelled during the first two years on the market, concerning doctors and patients attention to the fact that doctors are prescribing and patients are taking a medicine, which is not very well described and with the risk of unknown adverse effects. The label could also refer the doctors and patients attention to the reporting system of adverse effects.

Another labelling system could involve wellknown medicines, with which there are good experience, that are well described and the adverse effects are well known. Many of these medicines could be safer and cheaper to use compared to new medicines. These two initiatives could improve patients safety and could also improve pharmacovigilance.

With kind regarsd

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