EPSA EC CONSULTATION:

STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE:

PUBLIC CONSULTATION ON LEGISLATIVE PROPOSALS

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Executive Summary:

The European Pharmaceutical Students' Association (EPSA) is an independent, peaceful, democratic, non-political, non-profit European organisation committed to the interests of pharmacy students, and the ultimate benefit of society. EPSA is mainly an association of associations.
EPSA is a student organisation that represents over 120 000 pharmacy students from 33 European countries.

EPSA works under the motto:
Bringing Pharmacy, Knowledge and Students together.

Pharmacovigilance is the process of monitoring the safety of medicines and taking action to reduce risks to the public. Pharmacists can help in this by monitoring for unrecognized adverse drug reactions (ADR's), assessing the risks and benefits of medications, restricting and changing the legal status of a drug for example from an over the counter (OTC) to a prescription only medication and to promote the importance of reporting ADR's to the public so as to ensure appropriate pharmacovigilance. Thus this consultation is of direct interest to EPSA when representing the views of pharmacy students.

Introduction:

EPSA feels that as a student association representing pharmacy students all across Europe the views of students about changes in the legislation which they will eventually experience themselves in their professional lives is very important. We decided to focus on section 3 of the EC consultation as we believe that this is the section we can comment constructively about. The document is divided according to the EC consultation following the subtitles in section 3.

Section 3 Legislative strategy and the key proposals for legislative change

3.2.1. Fast robust EU decision-making on safety issues by rationalizing the existing EU referral procedures and reinforcing the committee structure.

EPSA believes that one of the main aims of pharmacovigilance is ensuring that the patients/consumers of a medicinal product are protected and adverse reactions are avoided as much as possible. EPSA agrees that establishing a committee structure with pre-defined roles would help in making the system of reporting pharmacovigilance issues

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and the way they are dealt with more transparent and more efficient and will result in the safety of the general public in all member states.

3.2.2. Clarify / codify roles and responsibilities and codify standards for industry and regulators

EPSA believe that codifying the responsibilities of all parties involved in drug production process and ensuring that standard operating procedures (SOP's) and Good Manufacturing Practice (GMP) are maintained is one of the key features in ensuring a more cost – effective and high quality service which will ultimately result in the benefit of the public and public health in general as high quality in production is maintained all throughout the member states. Codifying responsibilities and ensuring that the roles of the Qualified Person Responsible for Pharmacovigilance are followed according to Volume 9A of the guidance document on pharmacovigilance are adhered to will be of benefit to all involved parties.

3.2.3. Simplify informing the authorities about the company pharmacovigilance system

EPSA believes that this reform to the legislation will be extremely welcomed by the pharmaceutical industry. It will definitely save time and make the process much more efficient however we feel the need to stress that this should not be at the risk of any missing data and it should be ensured by responsible bodies that the 'Pharmacovigilance system master file' is actually available should it be required.

3.2.4. Rationalize risk management planning

Risk management plans are useful in the education of healthcare professionals on specific risks associated with medicinal products; they are also useful in avoiding medication errors and are definitely required to ensure appropriate pharmacovigilance. Industries should be encouraged to provide this information as it is also beneficial for them in avoiding legal proceedings against the company in the case of serious ADR's associated with a particular medication. We feel that Industries should be educated about the need of a risk management plan and ensured that this increases their credibility.

3.2.5. Codify oversight of non-interventional safety studies

Non – interventional safety studies add credibility and ensure high quality to any product on the market thus benefiting public health in general. EPSA agrees with the importance of this amendment in the legislation.

3.2.6. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports

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Simplifying the way reporting ADR's will make this process much more efficient, it will ensure that reports are dealt with in adequate time and manner as well as encourage co – operation from healthcare professionals by avoiding excessive paperwork and duplicate work. Creating a easy to follow procedure where all required forms are even available online or were reports can be done easily through an online procedure might be useful in making reporting ADR's much more efficient.

3.2.7 Simplify and make proportional to risk periodic safety update report submission by industry (PSURs)

This change will also increase the efficiency and therefore quality of pharmacovigilance and avoid duplicate work and therefore save companies money which they can spend on increasing the overall quality of the products produced.

3.2.8. Strengthen medicines safety transparency and communication

Encouraging transparency and coherent information given to patients and healthcare professionals will lead to better co – operation and trust from the public. This is something that should be enforced on both a European and national level.

3.2.9 Clearer safety warnings in product information to improve the safe use of medicines

We believe that this is one of the most important changes presented in the legislation. Unfortunately patients do not always remember the advice given to them by their healthcare professionals; many are on a polypharmacy regimen and sometimes even forget to mention that they are taking medications for chronic conditions when being prescribed other medication or purchasing OTC's. Providing them with clearer information and signs on the products will definitely be of benefit to general public health and supplement healthcare professionals work. The space available for signs on the product box is sometimes limited thus we suggest a system similar to the road sign system where icons which are understood by everyone are placed on the box – this would require an educational campaign but we feel that it would be beneficial in enforcing this legislative change. We also think that material should be printed in a slightly bigger font as this would encourage older patients to read them and using bright and appealing colors for warning signs.

Final Remarks

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EPSA agrees with the legislative changes proposed by the European Commission and welcomes the new changes and better quality in the field of pharmacovigilance.

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