European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

EIPG POSITION PAPER ON THE REVISED EUROPEAN PHARMACEUTICAL LEGISLATION

The European Industrial Pharmacists Group (EIPG) is a European association representing the national, and professional organisations of pharmacists employed in the pharmaceutical or allied industries of the Member States of the European Union, the European Economic Area, or European countries having a mutual recognition agreement with the European Union on compliance control of regulated medicines.

The Association is a Professional Group and is independent of all political parties and/or movements.

One of the underlying premises of the Association is to develop the pharmaceutical and allied industries in the interests of public health.

EIPG welcomes the opportunity to comment on the proposed revision of the European Pharmaceutical Legislation, which we see as important to the patients within the European Union.

Sustainability and Green Pharmacy

EIPG completely agrees with the need for sustainability within the pharmaceutical industry. However, this should be encouraged on a global level as to do so within Europe alone could put European manufacturing sites at a commercial research and development disadvantage concerning third-party countries.

To this end, EIPG has been debating what industrial pharmacists can do to help decrease the potential environmental impact from research, formulations, manufacturing conditions and product packaging to produce environmentally friendly medicinal products. We anticipate far greater discussion of green pharmacy.

EIPG wishes to encourage clinical trials and manufacturing within Europe and the revised pharmaceutical legislation does not appear to support this fully, therefore, the European Commission should consider the impact of the revised legislation on the ACT-EU initiative.

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Security of Supply

Although post-Covid the European Commission, the EMA and National Authorities have been taking a far greater interest in addressing shortages, they are addressing containment measures and not concentrating on the root causes.

As an example, it requires a better understanding of the pharmaceutical industry's manufacturing business model for established products because Europe should not be dependent on third-party countries for the large majority of active ingredients and the manufacture of many generic pharmaceutical products supplied to EU patients who are at the heart of our health systems.

Regulatory Data Protection

The complexity of the new modular system and the possibility of reduced exclusivity periods could disincentivise the launch of new drugs.

The impact of the legislation aiming to decrease disparities in access to medications across EU countries by offering two additional years of exclusivity to companies that launch in all member states within two years is admirable. However, the practicality of this goal is challenged by the current multiyear process required for a drug to reach the market with full reimbursement across the 27 member states, leading to drug launches well beyond the two-year target.

EIPG suggests that regulatory data protection is amended in a way to keep innovation in the pharmaceutical industry and also to allow patients early access to medicines.

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