PRESS RELEASE

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# The French Pharmaceutical Companies Association (Les Entreprises du Médicament) is calling for better information on medicinal products

Adverse effects from medicines understandably raise questions and cause significant concern for patients and their families. It is the duty of all parties in the health system to provide answers in the primary interest of safety for patients who have been prescribed these treatments.
The French Pharmaceutical Companies Association (Leem) has taken note of the solutions put forward by the Ministry of Health addressing mounting fears over 3rd and 4th generation contraceptive pills.

The Leem wishes to stress that medicinal products are marketed after a particularly demanding development process, in view of the favourable benefit-risk ratio, reevaluated regularly by the health authorities.

Contraceptive pills represent one of the greatest medical advances of the last forty years. As for any medicinal product, they present both therapeutic benefits and adverse effects.

These adverse effects – in this case venous thromboembolic events – have been known for many years, are widely documented, and feature in the marketing authorisation (MA), in the summary of product characteristics (SPC) and in the patient information leaflet. The risks are considered by both French and European health authorities and have led to recommendations for prescription. There has not been any failure of the pharmacovigilance system in this instance.

Besides the answers given in the particular case of oral contraceptives, the French Pharmaceutical Companies Association finds it regrettable that once again questions raised by a medicinal product – as legitimate as they may be – bring about a blanket accusation of the entire group of players in the system, from manufacturers to doctors.

It wishes to underline that medicinal products are particularly controlled substances, as much by public authorities as manufacturers, and that a major law for the reinforcement of medicinal product safety has been underway for over a year. This law aims specifically to improve pharmacovigilance and evaluation of a medicinal product throughout its entire life cycle, as well as reinforcing the transparency of links between the manufacturers of medical products and health professionals.

Pharmaceutical companies operating in France have supported the initiative to reform from public authorities and are committed to the deployment of new legal provisions.

Today, in light of questions raised by oral contraceptives, the French Pharmaceutical Companies Association wishes to stress that it supports the aim of improving the dissemination of health

authority recommendations among health professionals. Moreover, the association wishes to call for the reinforcement of initial and continued training of doctors on the medicinal product. Finally, it would like to highlight the importance of developing a clear system of information regarding the medicinal product, its development, the evaluation of the benefit-risk ratio, risks associated with potential misuse and the controls which take place right throughout the life cycle of the product, both at the level of the pharmaceutical companies and the health authorities.

The French Pharmaceutical Companies Association considers that the French public must have access to clear information regarding medicinal products. It is calling on the public authorities – on the basis of a diverse panel of experts - to commit to promoting information, education and raising awareness of medical products for patients and the general public in France. It is ready to endorse this approach through concrete actions, with respect to its own position. The aim is to restore conditions of a calm and rational debate on medicinal products.

*For all the latest information, go to: www.leem.org/espace-presse*

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