European Parliament
2014-2019

Committee on Petitions

30.7.2018

NOTICE TO MEMBERS

Subject: Petition No 0067/2018 by Francisco Almodóvar Navalón (Spanish) on a Single Protocol in relation to informed consent for HPV vaccination in the EU

1. Summary of petition

The petitioner is calling on the European Parliament to implement a Single Protocol in relation to informed consent for Human papillomavirus (HPV) vaccination in the European Union with the active participation of the EU health authorities. He refers to several principles in the Charter of Fundamental Rights, including the right to integrity and, in the field of medicine, the free and informed consent of patients. The petitioner claims that not enough information about the risk associated with HPV vaccine is being given to parents before the vaccination of their daughters, and that concerns about adverse reactions of the vaccine have been ignored.

2. Admissibility

Declared admissible on 14 May 2018. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 30 July 2018

The Commission's observations

The Commission notes that the competence for vaccination policies and how the national vaccination programmes are organised and implemented lies with each EU Member State in accordance with Article 168 of the Treaty on the Functioning of the European Union. As a result, vaccination programmes vary between Member States regarding aspects, such as being compulsory or voluntary, type of vaccines included, total number of doses administered, timing of vaccinations, and also type of healthcare workers responsible for the administration of vaccines.

EU law is in place to ensure that vaccines can be placed on the EU market only after a marketing authorisation has been granted either by a Member State for its own territory or by the Commission for the entire EU. In both cases, the authorisation is granted only after the quality, safety and efficacy of the product have been assessed on the basis of the results of a careful process of research, which includes clinical trials. The requirements and procedures for marketing authorisation, as well as the rules for monitoring authorised products, are primarily laid down in Directive 2001/83/EC[1] and in Regulation (EC) No 726/2004[2]. The safety of vaccines is monitored from the initial clinical investigation throughout the life cycle of a vaccine being marketed in the EU. The EU legislation requires marketing authorisation holders, national competent authorities and the European Medicines Agency to follow strict pharmacovigilance processes after a product has been authorised. This includes the analysis of new emerging safety information. Signals on safety risks are reported at the EU level and evaluated by the European Medicines Agency and regulatory action is taken, as appropriate. The Commission is assessing and monitoring the safety of vaccines through the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency.

Moreover, as for all authorised medicinal products, vaccine manufacturers are obliged by law to include information – in the language of the EU country where the vaccine is made available – about the safety and effective use of vaccines, including side effects and contraindications. This information is provided in the summary of product characteristics for healthcare professionals and the package leaflet for patients. This way, necessary information on the vaccine and on safe vaccine administration is readily available to both the health worker and the individual concerned before any vaccine is administered. Considering carefully this information contributes significantly to the safe administration of vaccines.

The above is true also for all Human papillomavirus (HPV) vaccines administered in the EU, for which authorisation is granted only after their quality, safety and efficacy have been assessed and which are accompanied by information – in the language of the EU country where the vaccine is made available – about their safety and effective use including side effects and contraindication. Moreover, as HPV vaccination is voluntary in the EU, only citizens who opt-in and give their consent are being vaccinated.

It is worth adding that in 2015 the European Centre for Disease Prevention and Control conducted and published a peer reviewed study on the safety of the two HPV vaccines that are authorised for use in the EU. This scientific study concluded that, based on the latest scientific evidence, both HPV vaccines seem to be safe.[3] More recently, in January 2018, the European Centre for Disease Prevention and Control released Guidance for the Introduction of HPV Vaccines in EU countries[4]. Its purpose is to lay down the scientific basis for the potential introduction of HPV vaccines in order to help EU Member States to make informed policy choices.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001on the Community code relating to medicinal products for human use

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[3] https://ecdc.europa.eu/en/human-papillomavirus

[4]https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/0801_GUI_Introduction_of_HPV_Vaccines_in_EU.pdf

The Commission has recently taken further action in the area of vaccination. On 26 April 2018, it adopted a proposal for a Council Recommendation and a Communication on strengthened cooperation against vaccine preventable diseases. This proposal calls for EU-level action to strengthen cooperation and coordination between EU countries, industry and other relevant stakeholders and proposes actions which the Member States could consider. The Recommendation envisages the possibility of establishing a web-portal with reliable updated information on the benefits and safety of vaccines, as well as on the pharmacovigilance process. The Commission's proposal recognises the pivotal role of healthcare workers in patients' protection and proposes measures in order to ensure the adequate training of healthcare workers on vaccination and to increase their vaccination coverage rates. These measures should contribute to the dissemination of accurate and objective information about vaccines, including about the HPV vaccine, and to equipping healthcare workers with adequate skills and knowledge regarding vaccines and vaccination for the benefit of their patients.

Conclusion

The Commission can only act within the framework of its competences, and most of the issues raised by the petitioner are beyond them. The Commission is currently not considering further actions in light of the principles of subsidiarity and proportionality, and considers that the relevant actions and objectives can be better achieved at the level of the Member States. As regards the safety of HPV vaccines, the Commission reiterates that a solid legal framework is already in place which ensures that only safe and effective vaccines are authorised for use in the EU and which requires marketing authorisation holders, national competent authorities and the European Medicines Agency to follow strict pharmacovigilance processes after a vaccine has been authorised.