MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

Informative Note

Spanish Agency of Medicines and Medical Devices AEMPS

THE AEMPS ADVANCES IN ITS ACTIONS TO ADAPT TO THE BREXIT

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The Spanish Agency of Medicines and Medical Devices wishes to inform of its ongoing actions to face the increased activity derived from the Brexit, including the expression of interest of external experts, the selection of new positions and the restructuring of its staff.

The United Kingdom's withdrawal from the European Union (EU), the so-called Brexit, has two main consequences for the Spanish Agency of Medicines and Medical Devices (AEMPS in Spanish).

The first of these is the need to adapt its structures so as to cope with, in collaboration with the rest of the EU Agencies, the numerous activities that the UK will stop doing in the context of the centralised and decentralised procedures. The European Commission has appealed to the solidarity and commitment of the Member States asking them to increase their operational capacity including both the ongoing procedures and those in the future, as well as the direction of the working groups that until now has been carried out by professionals from the United Kingdom.

The second is to provide support to the European Medicines Agency (EMA) in the event of the relocation of its site in Barcelona under the terms provided in the candidacy[1] presented in the month of July, with the aim of guaranteeing the continuity of its activities at the same high standards it has been providing in its services The procedure for the selection of the new site is expected to be finalised in November and Barcelona is one of the best positioned cities in the competition to house the EMA.

[1] Barcelona seat of the european medicines agency

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In this double context, the AEMPS announced an action plan in June that included different measures to adapt to the Brexit. The aim of this informative note is to provide information on its development.

Firstly, the AEMPS has started to carry out activities that, without the Brexit, could have been taken on by the United Kingdom. For example, the representative of Spain has assumed by election the position of chair of the CMDh (Coordination Group for Mutual Recognition and Decentralised Procedures), a key group in the EU given that in this group the activities related to the immense majority of medicinal products authorised in the EU are coordinated. In addition, the assessment of the first centralised procedures are already being initiated, whose duration will extend beyond March of 2019 and, therefore, are not able to be taken on by the United Kingdom. In order to cope with all these tasks, the AEMPS has proposed a functional restructuring of its staff that allows it to have an organisation more in line with the new situation.

Secondly, in September, the Ministry of Health, Social Services and Equality (MSSSI in Spanish) announced a process for the selection and naming of 40 positions of interim civil servants of the Technical Scale of Administration of Autonomous Bodies, speciality of Health and Consumption, to be stationed in the AEMPS for the reinforcement of activities of assessment, administration and inspection in European processes of authorisation of both medicinal products for human use and veterinary medicinal products. More than 1,100 applications have been presented for this public call, which continues to be within the time limits stipulated, and it is foreseen that the people selected will be incorporated in January of 2018. With this call, work areas covering all the activities of nonclinical assessment, quality of chemicals and biological products, clinical assessment, pharmacovigilance, administration or inspection will be strengthened.

Thirdly, the AEMPS opened a continuous call in July whose objective was that healthcare professionals and members of the academia expressed their interest in participating as external experts in the regulatory activities of the AEMPS. Two hundred professionals have formalised their inscription in this register and another two hundred are currently finalising this phase of the process. These are healthcare professionals, the majority from the National Health System, with experience in different areas related to both medicinal products for human use and veterinary medicinal products, among which are included the quality of medicinal products (70), clinical assessment (104), subjects related to clinical trials (93), the assessment of environmental risks (8), or pharmacovigilance and risk management (121). These professionals that have expressed their interest, have become part of a roster of experts managed by the AEMPS whose technical staff will contact them according to the needs and the procedures open, at that time

proposing to the experts their participation in said procedures whether it be at a national or international level.

Finally, the AEMPS together with other directive bodies of the MSSSI continues to develop the actions related to the Public Employment Offer of 2016 and 2017 that will allow consolidation of a part of its staff.

With all these elements, the AEMPS continues to face the solidarity commitments made with the rest of the Member States the European Commission and the EMA in order to guarantee European citizens that the Brexit has no consequences for the accessibility and availability of medicinal products as well as maintaining the highest standards of quality with which the Medicines Agency Network of the EU has been acting in benefit of patients.

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