LETTERS

Advancing Hospital Pharmacy Practice Through New Competences in Advanced Therapy Medicinal Products

To the Editor. As stated in the European Association of Hospital Pharmacists 2011 policy on specialization, additional competencies are necessary to fully understand the processes in hospitals and to manage the specific requirements of certain patient groups that are not otherwise frequently present in other fields of pharmacy, such as specialist practice in areas such as oncology, radiopharmacy, advanced therapies, and pediatrics. Among these areas, advanced therapies (including gene and cell therapy and tissue engineering) have hardly been developed in the hospital pharmacy practice, either in the United States or in Europe. Actually, these therapies are merely mentioned through the pharmacy residency programs.

With the introduction of EU Regulation 1394/2007 in December 2008, all cell products that are substantially manipulated prior to clinical application have to be regarded as medicines, meaning that hospital pharmacies in Europe are responsible for these products and have to oversee all aspects of their use in the hospital. Furthermore, gene therapy medicinal products are commonly already considered as drugs. Although some cellular therapy products have been approved, the Food and Drug Administration has not yet approved any human gene therapy product for sale, but a first gene therapy drug is already marketed in Europe. However, the amount of cellular and gene therapy-related research and development continues to grow at a fast rate, arising to introduce them by far in the current pharmacotherapy during the following years.

Advanced therapies allow enhancing the role of pharmacists in health-system decisions concerning selection, use, and management in hospitals. Using the same principles as those of the medication formulary system in which decisions are based on clinical, ethical, legal, social, quality-of-life, safety and pharmacoeconomic factors that result in optimal patient care and include the active and direct involvement of physicians and other healthcare practitioners. However, hospital pharmacy training in these new technologies requires a stepwise process to be familiar with highly technological and scientific concepts, that provides a complete new knowledge paradigm for most pharmacists.

Competences aimed at advanced therapy medicinal products (ATMPs) should include theoretical and practical skills in molecular and cell biology (such as cell imaging or flow cytometry), as well as their application to gene therapy, cell therapy, and tissue engineering. These new competences require further training in good manufacturing practices (GMP) for ATMPs and translational research related to hospital pharmacy challenges. Moreover, the implementation of ATMPs represents new strategic opportunities for hospital pharmacy development, such as ATMP noncommercial bioproduction, quality management, new process controls, regulatory policies and procedures, clinical implementation and development of pre-clinical and clinical research.

As a first step, in our institution we initiated a training program that allowed a hospital pharmacist specialist to advance in proficient competences with ATMPs management, implementation, and research through a postresidency fellowship grant. This program was focused in the acquisition of competences of management, implementation, and research of ATMPs, as well as its translation into clinics, and the role of hospital pharmacist as a promoter of these technologies in healthcare. Aimed competences in ATMPs included theoretical and practical skills in molecular and cell biology, as well as their application to gene therapy, cell therapy, and tissue engineering.

Targeted goals were accomplished by completing several training periods in different research and clinical facilities. Further training in clinical research was performed in an accredited GMP hospital facility for ATMPs. Competences in ATMPs included development of translational research projects related to hospital pharmacy challenges as ATMPs vehicle delivery, ATMPs pharmaceutical compounding, quality control, regulatory framework, pharmacovigilance, biosafety, or risk assessment. The expectation that pharmacists will be leaders in improving medication therapy outcomes necessitates a workforce composed of pharmacists with various levels of training, including traditional drugs, biologics, and advanced therapies.

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REFERENCES