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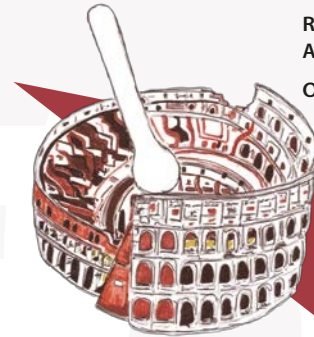
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*The evolution of the health service
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Abstract 075**USE OF AN AUTOMATED SYSTEM FOR THE PREPARATION OF BIOLOGICAL DRUGS AT THE INTERDEPARTMENTAL CENTRALIZED STAGING PROGRAM (PIAC)**

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Healthcare facilities have been trying, over the years, to overcome the critical elements related to the preparation of chemotherapeutics in order to ensure greater patient safety, lower risk of contamination for healthcare workers, and cost reduction. The preparation of antineoplastic therapies, in fact, represents one of the criticalities present within Hospital Organizations because of the complexity of the entire drug pathway. Highlighting the importance of an automated system within the PIAC in order to improve the sterility of the preparations through the minimization of manual manipulations, eliminating dosing errors through the use of automatic gravimetric control that allow, therefore, to achieve a high level of safety during the operative phases. Our center is the only one to use an innovative device capable of automatically preparing solutions of chemotherapeutic drugs in a controlled atmosphere. Such a system has been employed in our Laboratory for biological drug preparations, including for non-oncological indications. For its proper operation, it requires connection to a computerized system for managing chemotherapeutic preparations, whose graphical interface allows the entry and monitoring of all data necessary for scheduling activities with the requesting departments, including the management of data on materials of use (drug bottles and final containers), preparations to be performed, and patient master data. The dispenser, designed for single-patient liquid-phase drug preparation, allows loading of up to 16 bottles for up to 12 final containers, after Joblist generation on the graphical user interface of the computerized system. Automated preparations were set up with biologic drugs such as Natalizumab, Rixathon® and Ocrelizumab for the needs of the requesting OUs. The accuracy of the formulation was ensured by a real-time gravimetric control system capable of assuring dosing accuracies up to 1 percent, which are more than an order of magnitude higher than the precision allowed by the European Pharmacopoeia in manual preparations. Each dose is identified through codes that allow traceability with preparation and patient data. The establishment of a multidisciplinary team of hospital pharmacists, physicians, and nurses, through the management of daily therapy forecasts and with the standardization of the process, has also resulted in time savings. The implementation of the automated system within PIAC has resulted in increased safety for staff, sterility of the preparation, accuracy of the formulation, and traceability of the final product.

Keywords: Preparation traceability, Accuracy formulation, Sterility of preparation.

Abstract 076**EVALUATION OF THE IMPACT OF THE NEW EUROPEAN REGULATION (2017/745) ON PROCUREMENT OF MEDICAL DEVICES IN THE HOSPITAL PHARMACY OF AN ONCOLOGY IRCCS**

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In May 2021, EU Regulation 2017/745, which fundamentally changed the regulations governing the production and marketing of medical devices (MDs), became applicable, with the aim of au-

ment their level of safety and to review the roles and responsibilities of those involved in the production and distribution system. However, the adaptation of DMs by suppliers has led to difficulty in procurement by hospital pharmacies. This work aims to evaluate the clinical and economic impact of the new EU Regulation on DM procurement in the pharmacy of an oncology IRCCS. An analysis was conducted, during the period from January 2022 to May 2023, of DMs impacted by temporary or permanent unavailability issues (ceased marketing) within the hospital pharmacy. During the period under review, difficulties in ap- provisioning were found for 444 DMs managed by the warehouse (57.7 percent of the total). This was mainly attributable to delivery delays due to stock breakages, shortages of raw materials and materials used for packaging. For 84 DMs, replacement with similar devices was necessary. In 39 cases, the devices were replaced because the supplier reported that they were no longer on the market due to a lack of CE recertification, while, the remaining 45 were replaced due to protracted delivery times, which were often not adequately and timely communicated. With regard to DMs replaced due to failure to recertify, the expenditure incurred by the Institute for procurement increased by 34.07%, while for DMs replaced due to temporary unavailability, the expenditure decreased by 5.06%. However, overall, the expenditure incurred by the Institute decreased by 2.47%, as the DMs replaced due to temporary unavailability were those with the highest volume of consumption. In 4 cases (4.76%), it was not possible to proceed with purchase of a similar device because the device to be replaced was found to be infungible. The DM classes that were most affected by approval issues were: devices for administration, sampling, and collection (A, 27.38%), patient protection devices and incontinence aids (T, 21.43%), and suture devices (H, 13.10%). The new EU Regulation 2017/745 certainly ensures high levels of of marketed DMs, however, it has led to greater supply difficulties. Therefore, the role of the hospital pharmacist is crucial to limit the negative impact on the clinic and contain hospital spending.

Keywords: medical devices, EU Regulation 2017/745, Oncology.

Abstract 077**EUROPEAN MEDICAL DEVICE NOMENCLATURE SPEAKING ITALIAN: THE EXTRAORDINARY REVISION OF THE NATIONAL CLASSIFICATION OF MEDICAL DEVICES: EMDN V.0**

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The National Classification of Medical Devices (CND) groups medical devices into homogeneous categories of products intended to effect a similar diagnostic and/or therapeutic intervention. In 2007, with the publication of a decree by the Ministry of Health Italy decided to equip itself with a classification tool to photograph and to govern the medical device sector, which is characterized by complexity and heterogeneity. To better represent the market, include the entire panorama of devices on the Italian territory, and also ensure representation of technological evolution, the structure of the CND is expected to be revised periodically. Following the adoption Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, the European Commission identified the Italian classification system as the basis for the definition of the nomenclature (European Medical Device Nomenclature, EMDN) provided for by the aforementioned regulations.