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Implementation of regulation on labelling, patient information leaflets and summary on product characteristics on human drug products of natural origin

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Through marketing application process, the medicinal products are selected before they are marketed, and labelling, patient information leaflets and summary of product characteristics (SmPC), are reviewed in order to assure that the information is true and scientifically based. The aim of this work was to evaluate the implementation of the Regulation 14-2009 on labelling, patient information leaflets and SmPC on locally manufactured human medicinal product of natural origin. Comparison between the current regulation and its previous version considering relevant indicators and also the characterization of all approved texts from 2010 till January 2018, were made. The main changes found were related to the structure and content: new statements for special storage conditions, statements for 63 excipients with risk of adverse reactions, considering the route of administration, threshold, and declarative statements of warnings and precautions are included. SmPC was introduced for information for health professionals. Aspects related specifically to the natural origin of the medicine were also included like: plant name, extraction solvent, and quantity of active marker. There is no INN´-s for herbal preparations; therefore the use of an abbreviated form of the name for the substance was implemented, in agreement with EMA, for haemophatics: starting material and origin, dilution grade, recommended uses, other attributed or demonstrated properties were listed. Since the new regulation was implemented, 150 labels, 24 patient information leaflets and 13 summary product characteristics were uniformly approved for medicines of natural origin. Warning for lactose, ethanol, sucrose, tartrazine, and propyleneglycol were included. In conclusion, the new regulation is considered as a permanent powerful tool for manufacturers and the Cuban Drug Regulatory Authority, and provides an effective way to promote rational and safe use of medicinal products of natural origin for all distributors, users and healthcare providers.

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