1.- Introduction to GEMEH

Hemoderivatives are a class of drugs composed of blood proteins obtained, at least initially, from the plasma of healthy human donors. Given their complex protein-based structure, they cannot be obtained through chemical synthesis methods applied to pharmacological synthesis. They are instead obtained by industrial processes, through complex technological methods involving both selective plasma fractionation (plasma derivatives) or biotechnology (recombinant products). Moreover, they constitute a pharmacological class which must include specific purification, inactivation and/or viral removal steps in their manufacturing process. This process results in medicines used for a wide range of conditions, essentially to address congenital or acquired deficiencies of the circulatory or immune systems. Given the characteristics of their manufacturing process, these drugs are associated with a series of specific characteristics at the level of prescription, dispensing and administration that must be taken into consideration at the different stages of the patient's clinical journey.

One of the main characteristics of this drug class is that they possess a complex protein-based structure, which means that the must be administered by the parenteral route. Plasma fractionation also results in a wider variability of inter-batch characteristics, which must be considered. On the other hand, their protein content is high, both because of the active ingredient itself and because of the accompanying plasma proteins. Given the fractionation, purification and inactivation they are subjected to, a significant proportion of these proteins exhibit an altered structure.

Certain hemoderivatives such as recombinant coagulation factors, are obtained from genetic recombination processes. Genetic recombination has become a popular alternative to hemoderivatives obtained from plasma fractionation for two main reasons. On the one hand, plasma is a scarce raw material whereas genetic recombination can be used to obtain virtually unlimited amounts of blood proteins. On the other, recombinant derivatives are not associated with the risk of transmitting the so-called transfusional viruses.

When these drugs are administered and dispensed, it is advisable to conduct a personalized control of each batch, given the significant inter-batch variability observed and the potential adverse reactions to certain batches.

The main hemoderivatives in therapeutic use are coagulation factor concentrates (factor VIII, factor IX, factor VII, factor XIII), prothrombin complex concentrates (factors II, VII, IX and X), polyvalent and/or specific immunoglobulins, albumin, fibrinogen, the C1-esterase inhibitor, alpha-1-antitripsin, fibrin adhesives and antithrombin III.

The use of these drugs in clinical practice is not without controversy, as in some conditions they are employed in off-label indications not supported by clinical trials. For some indications, such as hemophilia, there are no clear criteria whether to use plasma-derived or recombinant products.

These drugs are used for different conditions by different specialists. Pharmacy departments are asked to procure and dispense these drugs by different hospital departments, often without a clear understanding of how they are used in specific conditions Indeed, specialists tend to use hemoderivatives according their own judgement, which may not be aligned with the approved indications. This, together with the fact that these drugs are usually used in case of emergency, places hospital pharmacies in situations where they must dispense them in situations far from ideal for an appropriate pharmacotherapeutic follow-up of the patient, which may compromise the traceability and safe administration of the medicines in question.

On the other hand, because of the complex process involved in the sourcing and manufacturing of these products, they constitute a costly class of drugs for health systems, accounting for a significant proportion of the budget of hospital pharmacies.

For the reasons outlined above, different scientific societies should establish clear criteria for the use of hemoderivatives. In this regard, the Spanish Society of Hospital Pharmacists cannot be oblivious to its duty to establish a set of criteria for the management and use of these medicines.