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.

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.

2. Rationale and goals

Hemoderivatives are a class of drugs 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.

In addition, the cost of the hemoderivatives used to treat congenital coagulopathies has traditionally been defrayed by the leading coagulopathy units in the country. However, now that the devolution of healthcare competencies to all the different autonomous regions has been completed, each region will have to cover the cost of treating their patients. In this regard, some regions have had to face the high cost of the treatments dispensed by their hospitals' pharmacies sometimes without a clear understanding of the drugs used or of the possible alternatives, that is, without being able to justify the expense to the hospital management.

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.

With this in mind, a specific workgroup on hemoderivatives (GEMEH) has been created within SEFH, with the following goals:

1. To provide the pharmacists of Spanish hospital pharmacies with an understanding of the characteristics of hemoderivative drugs as well as of their management, use, overall therapeutic positioning, pharmacotherapeutic follow-up, conservation, traceability and administration.

2. To establish, based on a general consensus, the criteria required for an appropriate use of hemoderivative drugs for different conditions.

3. To foster and facilitate the conduct of observational research projects, aimed at gaining a better understanding of how such medicines should be used. To foster and facilitate the conduct of clinical trials aimed at evaluating the efficacy and safety of hemoderivatives in areas where there is still certain uncertainty regarding their real therapeutic use.

4. To promote pharmacoeconomic and health outcome studies in order to gauge the real impact of hemoderivatives in terms of their cost and outcomes, within the context of the different therapies administered.

5. To set guidelines that may be used to advise hospital pharmacists about the way the different hemoderivative drugs (coagulation factors, prothrombin complex, albumin, immunoglobulins, etc.) should be managed and administered.

3. Methodology

To achieve the goals stated above, a workgroup will be created made up of hospital pharmacists routinely involved with hemoderivative drugs. The workgroup members will be professionals with experience in the management of hemoderivatives who work in hospital pharmacy departments. The idea is for the GEMEH workgroup to

include at least a hospital pharmacist from each of the hospitals that possess a congenital coagulopathies unit, with a maximum of 8 members.

The workgroup will also collaborate in educational activities addressed to hospital pharmacists.

Meetings of the GEMEH workgroup will be convened at least three times a year. Specialists from other disciplines may also be invited to the workgroup meetings so as to gather the required expertise to prepare consensus documents leading to the attainment of the workgroup's objectives. A consensus document will be prepared at each meeting, containing the ideas that participants may have contributed on the topic discussed.

Smaller workgroups will be created to dwell on the different classes of hemoderivatives: coagulation factors, immunoglobulins, prothrombin complex, factor VII, etc.

Smaller workgroups will also be created to evaluate, promote and implement research proposals and projects resulting from an initiative of the GEMEH workgroup or of any SEFH member.

4. GEMEH workgroup funding

The hemoderivatives workgroup will, in principle, obtain its funding from external sources.

5. SEFH members supporting the establishment of the GEMEH workgroup

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