In My View

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On a regular basis, we see and hear the debate about cost-saving measures for pharmaceuticals. Too often is our sector immediately drawn into this debate because many persons do not understand why we are so different from what we call traditional pharmaceuticals. In this column, I will try to summarize the arguments again.

Plasma protein therapies (PPTs) are used by individuals with rare diseases. Together these individuals make up small patient populations. We are not talking about the blood pressure medications, diabetes therapies, or psychiatric drugs that millions of people use. That in itself is already a differentiator. It has to be understood that the costs for the development and manufacturing of plasma protein therapies are borne by a relatively small group of individuals.

Some recipients of PPTs (e.g., persons with hemophilia) have a choice between therapies. These include plasma-derived clotting factors, recombinant clotting factors, monoclonal therapies, and even gene therapy. Other recipients of PPTs do not have a choice and depend completely on the supply of plasma-derived medicinal products. The manufacturing of these therapies is very different than products made from chemical compounds.

The starting material for PPTs is human plasma from committed healthy donors who are willing to donate on a regular basis to help their fellow citizens. The number of plasma donations needed for a year of therapy is enormous: 130 for immunodeficiency, 900 for Alpha-1 Antitrypsin Deficiency, and 1,200 for the production of factor VIII. It is not difficult to understand that the costs to manufacture therapies from these many donations are substantially higher than the production of a chemical compound.

That is not all. It is just the beginning. There is a strict donor selection procedure that includes medical and diagnostic checks to ensure that the donor is not carrying an infectious agent. After the donation, the plasma is kept in inventory hold for at least 60 days before the manufacturing can start. This adds a level of safety because it allows for post-donation information to be provided. If that information indicates any reason for donor disqualification had the information been available at the time of donation, this added step ensures that the industry can trace this donation and discard the donation before the manufacturing process starts. Having the plasma inventory sitting in storage for 60 days is an enormous financial investment that does not exist for other industries.

Then the manufacturing process starts and involves separation, purification, and viral inactivation, just to name a few requirements. Every step involves robust quality control and quality assurance measures. Even after the distribution to a patient, monitoring and vigilance continues.

Unlike the manufacturing of traditional pharmaceuticals, the time between the plasma donation and distribution to the individual who needs therapy averages between seven and 12 months!

It is good to see that more and more persons are starting to understand why this industry is unique and cannot be subjected to the same cost-containment measures as we see for pharmaceutical drugs. But it is not enough. We need to continue to help more people understand the different nature of our industry. •