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IN MY VIEW

CONTINUED CHALLENGES OF DOING BUSINESS IN JAPAN

IN THE PREVIOUS EDITION OF THE SOURCE I wrote about the challenges of doing business in Japan. One of the issues that I mentioned is the Japanese labeling requirement. Manufacturers of plasma protein therapies are required to print on the label whether the origin of the starting material is “Kenketsu” or “Hikenketsu.” In the column I wrote that Kenketsu applies to therapies manufactured by domestic manufacturers and Hikenketsu to therapies manufactured by foreign manufacturers. The Japanese Ministry of Health, Labour and Welfare (MHLW) communicated their displeasure with this and requested that PPTA print a correction. According to the email from the MHLW, the correct translation is:

Kenketsu : Voluntary, non-remunerated donation

Hikenketsu: Not voluntary, non-remunerated donation

I am happy to print the correction but must say that it is very confusing now. The etymology of the words kenketsu and hikenketsu are really not important. The basis for my argument is the artificial differentiation between two safe and effective therapies resulting in reduced demand for one of them. Does someone really believe that our members are using donors who donate against their will? That is far from the truth. The vision of “non voluntary” donors being chased while their plasma is forcefully “donated” is more than a little farcical. Seriously, however, I continue to believe that there should be no labeling requirement at all, since it can be used to discourage the import of safe and effective therapies to Japanese patients.

MHLW has set up a panel to make recommendations about the future supply of plasma protein therapies in Japan. PPTA was invited to address the panel on February 7.

We prepared a talk about the differences that we see in Japan and other parts of the world in regard to plasma collection and the use of therapies. In our presentation we addressed several challenges in Japan, such as:

- No increase in plasma for fractionation for many years
- Immune globulin consumption has been stable for decades, unlike the rest of the world
- Primary immune deficiency in Japan is under diagnosed
- Self sufficiency policy has had a negative impact on access to therapies
- Limited scale of economics for domestic manufacturers
- Discouragement of innovation for foreign manufacturers
- Plasma protein therapies are used by small patient populations

- Low number of repeat donors in Japan = high dependence on new donors
- Limited collection of hyper-immune plasma in Japan
- Availability of hyper-immunes is limited
- Anticytomegalovirus (Anti-CMV) Immunoglobulin is not available at all
- Anti-Zoster not available at all
- Current Yakka system does not work for plasma protein therapies

Even though we were scheduled for a 20 minute presentation including question and answer session, the panel wanted to discuss a wide variety of issues and the session lasted an hour. The questions ranged from basic information about plasma collection practices (recovered and source) to specific questions about clinical studies on albumin and albumin usage. Perhaps of greatest interest to members of the Panel were answers to questions relating to the global increase in consumption and usage of intravenous immune globulin (IVIG). During our presentation, we demonstrated that not only was Japan’s IVIG consumption below average for the rest of the developed world, but also showed that it is one of the very few countries that have not experienced an increase in usage over the past 20 years. We explained to the Panel that this is contrary to most of the IVIG using countries of the world where the use of IVIG has been steadily increasing due to recognition of its clinical benefits in terms of labeled indication, and the increase in the awareness and diagnosis of diseases that are treatable by IVIG. The final question asked of PPTA was the status of self-sufficiency policies as a global matter of policy. We responded by re-affirming the importance of local supplies of whole blood and transfusable components, but also noted that we as an industry are committed to global self-sufficiency and patient access to all safe and effective therapies. We are grateful that there are countries with committed donors who all donate voluntarily allowing us to manufacture therapies that can be used by patients all over the world including Japan.

We believe this meeting was successful in bringing our points of view across and we are looking forward to further constructive dialogue with MHLW with the goal to bringing more therapies to the patients who need them. 