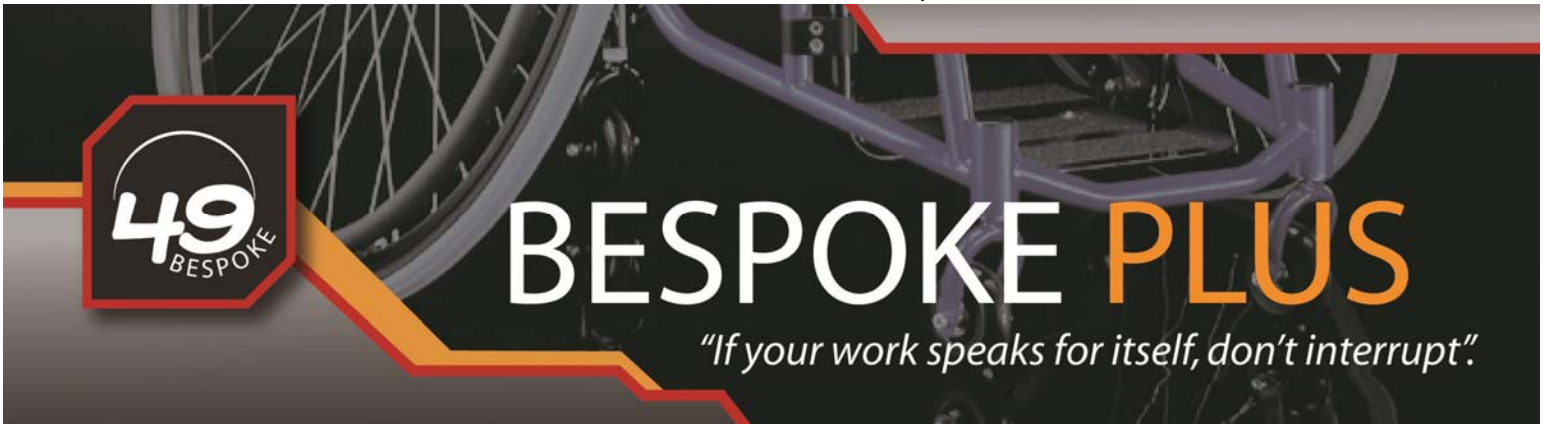

250% Fee Increase

"The *Food and Drugs Act* and *Controlled Drugs and Substances Act* and their regulations set out regulatory requirements that industry must satisfy in order to market a human drug or medical device in Canada. Health Canada is the federal authority responsible for regulating these products both pre- and post- market, and in doing so, protects the health and safety of Canadians who use these products to maintain and improve their health. "

If you are distributing or importing medical devices in Canada you require a license. Medical devices are classified into one of Classes I to IV by means of the classification rules where Class I represents the lowest risk and Class IV represents the highest risk.

The Medical Device Establishment License (MDEL) fee went from $2,120.00 as an annual cost to $7,200.00! A 250% increase to do the same job as last year. This takes into account a fee remission for companies that claim it based on 1% of their gross sales!

I am not sure if anyone else finds this somewhat obnoxious for Class I Devices (I can see that there is a lot more work required to police Class II, III and IV devices, but, a wheelchair designed to get a person from A to B!

Health Canada's mandate "is to promote good nutrition and informed use of drugs, food, medical devices and natural health products and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system". **They have provided the following information in support of their fee increase.**

Issue: The current user fees for regulatory activities related to human drugs and medical devices have not been updated since their initial implementation starting in 1995, and no longer reflect the costs of delivering services. This has resulted in increasing funding pressures on Health Canada and impacted its ability to meet internationally recognized service standards.

Description: These Regulations formalize the objectives of Health Canada's User Fees Proposal, approved by Parliament in May 2010, to update existing fees to provide a stable funding platform from which to provide regulatory service, and to contribute to Health Canada's priority of protecting the health and safety of Canadians. The Regulations also consolidate various existing user fees regulations and provide the following key elements:

1. establishing fees for regulatory activities and stipulating their amounts in a schedule or provision;
2. establishing timing and allotment of fees payable;
3. providing fee mitigation measures;
4. and adjusting fees annually.

Cost-benefit statement: The cost-benefit analysis supports these Regulations to update fees for services, which will generate additional revenues in the amount of $66.4 million.

These fees will help to cover increased cost to Government for evaluating the safety and efficacy of human drugs and medical devices, as well as monitoring and enforcing compliance of the relevant regulations. The overall net present value (i.e. the benefit) of these Regulations will be $639.9 million over 10 years.

Business and consumer impact: The updated fees are largely balanced by the benefits to consumers and businesses that accrue through the earlier entry of new drugs and medical devices as a result of Health Canada meeting its service standards.

In addition, these Regulations provide fee mitigating measures to address undesired impacts to businesses with small revenue streams.

Domestic and international coordination and cooperation: Consultations have been conducted with domestic and international stakeholders. Although foreign companies are required to pay fees for regulatory activities related to the sale of human drugs and medical devices in Canada, there is no expected conflict with international trade agreements or obligations.

Performance measurement and evaluation plan: Health Canada has developed a Performance Measurement and Evaluation Plan (PMEP), describing the commitments to planning, monitoring, evaluating, and reporting on results of these Regulations and overall cost recovery initiative. As required by the User Fees Act, Health Canada will report annually to Parliament on associated costs, revenues and performance. Where the Department is not able to meet service standards associated with user fees, the penalty provision of the User Fees Act, will apply.

We have end users ask about the cost of product every day, but it is way to cumbersome to go into the type of detail noted above on all the areas that impact the final cost of a product. For small to medium sized businesses, this is an obnoxious fee increase or additional tax. The dissenting opinion to this significant fee increase was acknowledged, but the direction is to have this industry pick up 50% of the cost; I would like to have some say into those costs because frankly I think that a lot of that money is flushed down the drain!

Panthera in Norway

Randy Willett, VP ***VARILITE®*** is pleased to announce that they have a new distributor in Norway. Panthera Norge is a company that was established to take sales of the popular Panthera wheelchair line to new heights in Norway. He is pleased that Panthera Norge is also distributing *VARILITE* products and relays that he looks forward to continued success in Norway with Erik Bergh, Managing Director and his team at Panthera Norge.

Chair of the Month

RGK has started a new initiative on their web site at www.RGKLife.com . They will be showcasing a custom chair of the month and they have chosen Hi-Lite from the showroom for the month of August. The Hi Lite is a classic RGK design, suitable for a wide range of users for whom lightweight and easy independent transportability is important.

RGK invites you to send in your custom chair imagery to share with others if you have done something different to customize your ride to meet specific needs. Click on the url above, news, and custom chair of the month heading.

Big Chairs Hurt

A chair that is too big can have harmful effects on the end users health and well being. Surfing the net you still see a lot of sites that encourage a seat width to include a lateral measurement from the widest points on the end user in a sitting position (between the lateral aspects of the greater trochanters) and then add two to four inches to accommodate potential growth, a winter coat, etc. No! Listen to the people who are getting around in that unit every day; measure outside to outside of the widest point and build the unit; and standard sizes are not 16", 18", and 20"'s; you can have whatever size you need.

It is harder to achieve pelvic stability in a chair that has an extra inch or two of width on either side of the end users body and that unit is harder to propel because of the angle that the end users arm is in relation to the wheel. That bigger chair takes up more room wherever the end user goes and is less appealing aesthetically as it engulfs the end user. So, for all the right physical and psychological reasons, please fit the chair to the size of the end user for the health of it!

Bits and Bytes

- Ottawa Trip August 31-September 02;
- REE Sept. 13 at the Armories in Vancouver, BC;
- OSOT Conference Niagara Falls, ON Sept. 23-24;
- Rehacare Sept 21-24 in Dusseldorf, Germany;
- SHHC Innovation Show Nov 14-15, Toronto, ON;
- SHHC Innovation Show Nov 29, Calgary, AB.

BESPOKE PLUS helps to market and promote ***RGK Wheelchairs***, ***VARILITE®*** Seating and Positioning Systems, ***KENDA,*** and ***Ki Mobility*** products, along with Spinergy, Glance, Frog Legs, Schwalbe, Sun, MBL, Natural Fit, Blax, and other great products.

Please give us a call or contact the editor, Reg McClellan, if you have something that you think we should expound on.