SCTO PLATFORMS

Patient-to-patient: Talking about medical devices

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How will the regulatory changes taking place for medical devices affect patients – those who carry the true risks or benefits of having them in or on their bodies?

For a down-to-earth patient perspective, European Patients' Academy (EUPATI) fellow Estelle Jobson met with Karen Topaz Druckman, President of the Swiss patient association, HHT Swiss, to ask her some questions. Karen's views represent years in patient advocacy including patient input.

The SCTO and its network of CTUs commented only on the ClinO-MD.

Medical devices are so frequently associated with scandals and stories of patients who have suffered bad or even fatal experiences. How do you think the future harmonisation between Switzerland and the EU of the regulation of medical devices might affect safety?

I think that this harmonisation is likely to lead to more rigorous trials and investigations. This in turn should improve the safety of devices. Specifically, collecting and sharing complaints, feedback, and adverse events centrally (including long after a device has reached the market), will allow alerts about safety risks to be communicated swiftly all across Europe. When reporting is *ad hoc* and/or local, it can take a long time before any one community realises that an incident in that community is not isolated, but has also occurred elsewhere. Devices that appear harmful or dangerous must be pulled off the market everywhere, as quickly as possible, to spare patients unnecessary harm or even death.

The new European electronic registration system of clinical investigations with medical devices (Eudamed), to be set up by the Commission, will facilitate centralisation. Perhaps even more important is the new requirement that failures, as well as successes, of trials be reported. Access to full information will help prevent unnecessary duplication of clinical trials, could save unnecessary costs, and give researchers the opportunity to build on actual trial results in the development and design of future trials. Such transparency also gives all stakeholders a chance to better evaluate the importance of any given study.

So safety and transparency are likely to improve. But is there a potential downside to the situation?

Some people believe there is risk that more stringent regulation (and the resulting costs) may cause some

devices – particularly those produced by small to medium-sized companies – to be removed from the market resulting in patients losing access to these devices. I would hope that the expansion of the market for any such device would offset that risk.

Can you give an example of a medical device that your patient community would like greater access to?

Yes, an excellent example exists in my patient community (people affected by Hereditary Hemorrhagic Telangiectasia (HHT), also known as Osler-Weber-Rendu Syndrome): nasal packing.

HHT is an inherited disease that leads to malformations of the vascular system in multiple organs of the body; it typically begins with nosebleeds. When people with HHT suffer debilitating nosebleeds, they are forced to go to hospital emergency services simply to stop the bleeding. It can be stopped by using a medical device: bioresorbable nasal packing that can be inserted into the nasal cavities to apply pressure to stop the bleeding, as well as to help prevent adhesions between mucosal surfaces, and promote healing. The packing dissolves and clears away naturally thereby eliminating the need for painful removal, which can trigger bleeding again.

It is a life-changing event for HHT patients to be able to manage their disease themselves by learning to insert the nasal packing rather than having to be rushed to an emergency medical facility. Having easy access to this medical device can spare them traumatic, time-consuming hospital visits, and associated costs. In Switzerland, however, HHT patients are not currently allowed direct access to this device. It is only available to medical professionals.

In Germany, however, HHT patients are able to access this medical device themselves. It is now even approved (thus reimbursed) by the health system. We hope that mutual recognition between Switzerland and the EU will ultimately get more devices into patients' hands, so they can manage their conditions as independently (and economically) as possible.

Do you have any thoughts on how the changes underway may affect the research and development of medical devices?

Yes, R&D is crucial to rare disease patients. These changes should allow Swiss medtech companies inventing and developing these devices to help more patients, and access to the EU market will hopefully provide a better economic incentive. Harmonisation of rules between the EU and Switzerland regarding the clinical investigations of medical devices will facilitate cross-border clinical trials, on larger numbers of participants than would be available nationally.

And finally, what other patient needs or constraints related to medical devices do you think are particular to Switzerland?

In Switzerland, patients are subject to the conditions of their medical insurance, which varies considerably from one policy to another. Availability of additional medical devices is a good thing, but for these devices to be accessible to patients they must be affordable and, therefore, at least partly reimbursable. The next step for Switzerland will be to insure reimbursement under basic health insurance for the new devices.

We sincerely hope that greater harmonisation for devices will promote equal access, for all patients Europe-wide. If the regulations and controls are the same, once one country (such as Germany, in the example above) authorises a device, other countries can rely on that country's analysis and follow suit and authorise it. This could represent a sea-change for patients – as well as for industry. Will HHT patients here be able to

access, use, and be reimbursed for the nasal packing, for example?

We hope government and insurance companies are listening attentively to patient requests and will be facilitating our access to the tools we need to live as well as possible, with our conditions.