Invitation to take part in Study on validation of new medical device symbols

MedTech Europe[1] will soon be conducting a Study on the validation of new symbols for medical devices to be used in medical device labelling in order to comply with the medical device regulation requirements.

Medtech Europe are hereby seeking patients' expertise in helping them to evaluate new symbols to be included in an international standard in the field of medical devices.

What is this study about?

The aim of this validation is to evaluate the use and meanings of new symbols related to medical devices for their possible inclusion in ISO 15223-1, international standard on labelling. This standard identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. The internationally recognized symbols are an efficient way of presenting key information on the product without having to use excessive text and translations. We therefore request that you answer the surveys by yourself, without any help (e.g., asking other people).

Some meanings currently do not have symbols associated to them, such as: contains animal tissues, contains human tissues, CMR (hazardous substances) and single patient multiple-use (which indicates a medical device that may be used multiple times (multiple procedures) on a single patient) for example. For this reason, MedTech Europe are developing brand new symbols and need them to be tested; in order to comply with the MDR (new) requirements.

Target groups: external: HCPs (doctors, nurses), patients

All responses will be evaluated anonymously and used only for scientific purposes.

How will the study be conducted?

The validation will be done through a series of surveys that will be made available to you step by step through an online platform.

Please carefully follow the instructions for each survey phase. There will be 3 phases over the next 2 months. You will always receive an email with the link to the survey and the deadline for completion. You will be able to save the work and login back later to finish it.

Please note the approximate timing of this validation exercise:

Approximate timing for high risk validation (testing 4 symbol meanings)

1. Appropriateness: 1st Feb – 14th Feb; 2 weeks.
2. Associative strength (This test involves providing several possible descriptions of each candidate symbol and allowing the survey taker to determine by ranking (high to low) which description best applies to the symbol image presented. All candidate symbols should be evaluated using their own surveys. The best candidate symbol will score highest in its testing.): 15th Feb – 1st March; 2 weeks

[1] MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. They represent Diagnostics and Medical Devices manufacturers operating in Europe.

3. Memory/usability: 2nd March – 16th March; 2 weeks (high risk symbols only). Label with symbols available only for 3hrs after opening the link. After 1 week, a new link with the 2nd sheet to match the meanings to the symbol will be sent, you will have 10min to complete.

What is expected from each participant? And how can you get involved?

- What is needed from you?

  - Your email address, indicating that you are a patient (i.e. belong to the patient target group and that you will undertake the high risk validation)
  - Around 30 mins of your time for appropriateness testing and similar for associative strength.
  - For memory/usability testing (where applicable) – time to familiarize yourself with a label and after 1 week 10 minutes to assign correct symbols to correct meanings.

- By taking part in this validation exercise you will be:

  - Playing an essential part in the revision of a key international standard in the medical devices field
  - Defining a more efficient & harmonised international practice, whereby information and warnings on products are easily understandable to all concerned.

To indicate your interest to participate in this study and get involved, please send your email address, indicating that you are a patient to: Jana Moravcova <J.Moravcova@medtecheurope.org> by the end of this week, **1 February 2019**.

For further information, please contact Katie Gallagher, katie.gallagher@eu-patient.eu