Submission to the consultation on the scope of regulated software-based products

Japan Industrial Radiology Systems Association (JIRA)

Australian Government
Department of Health
Therapeutic Goods Administration

Question

- What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

Comment

Patient analyzing/screening software based on mammography system could be exempted from inclusion in the ARTG as is related to “Software used by health professionals” on page 16. It says “software that analyses a group of patients for common trends or diagnostic indicators e.g. breast density and cancer propensity could be excluded or exempted” And the extension of the idea could lead to the exemption of even the analyzing/screening software. The reason is that it does not pose significant harm because whole procedure is controlled by health professional as long as it is used for patient analyzing/screening purpose and the final diagnostic decision is made by health professional.

Question

- What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

Comment

Some image processing/diagnosing software could be exempted or excluded from the oversight of TGA. As commented in the previous consultation on SaMD software-based medical devices originally have no direct interaction with patients or users. Therefore, they pose no direct harm. And some of the image processing/diagnosing software does not lead to definite diagnosis which requires health professional’s assessment. Some of them are based on long-standing technology and have been operated in the market without adverse events which does not requires detail control from TGA.

Question

- Please provide details:

of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or

describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

Comment

As is described in the previous comment the output of the screening/analyzing software of mammography is supposed to be assessed by health professional in terms of intended use of the device. If necessary, health professionals make diagnosis along with other information such as ultrasound image. In case of image processing/diagnosing software the intended use is also important along with the related labelling which should require health professional's decision on diagnosis. Therefore, intended use is considered as an important rule or pseudo-oversight.

Question

- Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?

Comment

For overall changes we would like to ask to avoid the inconsistency with Medical Device Regulation 2017/745. It may cause additional period for implementation and financial impact to manufacturers. Compared with MDR Classification Rule, TGA Rule is more complicated. Introducing new features such as indivisual/health professional, public health risk and therapy would be TGA's great effort to implement and interpret IMDRF SaMD Risk Categorization, but simplification to be understood by manufacturers is expected.