Implementing eIFU

Under EU regulation 207/2012 on electronic instructions for use for medical devices

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Alcon

I. Background: what made Alcon to go for eIFU?

1) <u>Fulfilling MDR requirements regarding website information</u>

MDR Annex I Section 23.1

"Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by **any safety and performance information relevant to the user, or any other person**, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and **shall, if the manufacturer has a website, be made available and kept up to date on the website**"

To address, Alcon decided to make all its IFUs available online.

I. Background: what made Alcon to go for eIFU?

2) <u>Moving to eIFU for products in scope of eIFU regulation 207/2012</u>

Since Alcon is making efforts for IFUs to be online Alcon decided to implement the Regulation 207/2012 for our ophthalmic implants in scope and to no longer include a paper leaflet with these devices.

Scope of eIFU reguation

(article 3(1)):

Scope to be extended by

May 2021 to include MDSW

for lay user)

(a) active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device;

(b) implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device;

(c) fixed installed medical devices covered by Directive 93/42/EEC;

(d) medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use;

(e) stand-alone software covered by Directive 93/42/EEC.

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II. Planning: what to consider to implement eIFU?

1) <u>Regulatory aspects</u>

   a) Risk management (article 4)

Identify the hazards linked to providing the IFU electronically instead of in paper format, and putting in place risk control measures.

Examples of risks:
- ✓ Risks linked to website security
- ✓ Risks linked to accessibility of the website by the user
- ✓ Website accuracy
- ✓ User errors

Output: Risk Management Report

Updated the Technical Documentation of the device (ERC, Risk management report, Usability engineering report.)

Applied for conformity assessment to the Notified Body (submitted as substantial change per NBOG BPG 2014-3 on reporting changes)

Notified Body review and approval before impementing

II. Planning: what to consider to implement eIFU?

b) Ability to provide paper IFU

Article 5(3): the manufacturer needs to be able
to provide a paper copy within the time period set out in the risk
assessment and at the latest within 7 calendar days
(or at the time of delivery of the device)
if requested by the user, at no additional costs

Alcon's experience: this service is provided by the vendor
supporting the IFU website. A phone number list is provided
as part of the labeling. The customers can reach out
to the vendor, request the paper copies, which will be
dispatched to them.

c) Understand and address the requirements in non-EU countries

Make a regulatory survey to understand in which non-EU
countries the IFU can be provided only electronically for the type
of devices for which you want to implement eIFU.

Plan for the cases where the paper IFU is mandatory.

Alcon's solution: paper format IFU can be added by redress at the
distribution center

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Argentina: +800 135 79 135	Luxembourg: +800 135 79 135
Australia: +800 135 79 135	Magyarország: +800 135 79 135
Austria: +800 135 79 135	Nederland: +800 135 79 135
Belgium: +800 135 79 135	New Zealand: +800 135 79 135
Brazil: +800 135 79 135	Norge: +800 135 79 135
Canada: +1 855 805 8539	Polska: +800 135 79 135
Česká Republika: +800 135 79 135	Portugal: +800 135 79 135
Chile: +31 20 794 7071	România: 0800 895 084
Colombia: +800 135 79 135	Singapore: 800 101 3366
Cyprus: +800 135 79 135	Slovakia: 0800 606 287
Danmark: +800 135 79 135	Slovenija: +800 135 79 135
Deutschland: +800 135 79 135	Suomi: +800 135 79 135
Ecuador: +31 20 794 7071	Sverige: +800 135 79 135
España: +800 135 79 135	Switzerland: +800 135 79 135
Eesti: 0800 0100567	Türkiye: 00800 142 064 866
France: +800 135 79 135	United Kingdom: 00800 135 79 135
Hrvatska: 0800 804 804	United States: +1 855 236 0910
Ireland: +800 135 79 135	Việt Nam: 122 80297
Ísland: 800 8996	България: +800 135 79 135
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II. Planning: what to consider to implement eIFU?

<u>2) Commercial aspects</u>

Survey your customers to understand how they appreciate receiving the IFU in electronic format only.

<u>Alcon's experience</u>: due to negative feedback from some customers, Alcon decided to still add the paper IFU for some countries for commercial reasons. This is also being added by redress activities at the distribution center.

III. Execution: How to implement eIFU?

1) Set up and website

Alcon's experience: Alcon worked with a vendor that has experience in providing this kind of services. The website hosting is a dedicated website, not a part of Alcon's general website.

Alcon implemented processes to prevent the shipment of products prior to IFU upload.

2) Include link to the website on the labeling (article 6(1))

IFU symbol followed by the general website url can be found on the secondary packaging.

The url is on every carton ; the website is searchable per model and com
name, per country and in the appropriate languages.

www.ifu.alcon.com

3) Communicate to customers (article 6(2))

Alcon's experience: Alcon implemented eIFU for intraocular lenses which are used by qualified surgeons. Alcon first trained its customer facing teams and developed a FAQ for use when communicating to customers. Then Alcon's marketing department trained the surgeons on how to use the website and find an IFU.

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