Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Guidance:

Medical device stand-alone software including apps (including IVDMDs)

All of the current legislation regulating medical devices is in the process of being revised at European level. This will replace the existing three European directives with two European regulations. This guidance applies to the current regulatory framework - new regulations may result in changes to the classification criteria for software medical devices.

http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en

Click for next page

We welcome comments on this document. Please send feedback to: **software@mhra.gsi.gov.uk**

- This document is intended to be viewed on screen rather than printed.
- Please use the in-document links to navigate through this document for further information on the CE mark process.
- At the bottom of each page you will find a navigation pane with quick links to the start of the main sections.

Click me

Get Started

Regulatory information is formatted like this.

MHRA comments are formatted like this.

Indicative words and phrases box:

Words and phrases listed in this box are all likely to contribute to a determination by the MHRA that the app they were associated with is a medical device.

See:
MHRA Guidance Note No. 8 – A guide to what is a medicinal product
and
Guidance on legislation, Borderlines with medical devices.

Quick links, click to fast forward

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Introduction

This guidance document replaces the previous MHRA guidance titled "medical device standalone software, including apps".

As well as medical device apps becoming a growth area in healthcare management in hospital and in the community settings, the role of apps used as part of fitness regimes and for social care situations is also expanding.

However, in the UK and throughout Europe, standalone software and apps that meet the definition of a medical device are still required to be CE marked in line with the EU medical device directives in order to ensure they are regulated and acceptably safe to use and also perform in the way the manufacturer/ developer intends them to.

Health related apps and software that are not medical devices can be extremely useful but fall outside the scope of the MHRA. Work in this area is being developed by the National Information Board in their Workstream 1.2

But how do developers and users of this software decide whether apps qualify as medical devices and which are for health and fitness purposes?

This guidance uses **examples within flowcharts** to show which standalone software and apps meet the definition of a medical device, an in vitro diagnostic device or active implantable medical device and therefore require to be CE marked, and those which do not.

For developers of software, including apps, we are also including information on classification, suggestions on how to address the main aspects of the CE marking process and responsibilities for reporting and correcting when things go wrong.

For users we offer a few tips on how to decide if the app or software device you are using is a medical device and if so how to ensure it is CE marked along with how to report problems

This guidance is to be used in addition to MEDDEV 2.1/6 and is the UK's interpretation of the guidance.

Developers and manufacturers

Users

The manufacturer is defined as:

"the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party."

Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices

Software users – professional and lay

How do I know if my app is a medical device?

If you are using an app for yourself or if you are using an app and you are not a trained healthcare professional, then this advice is for you. If the app you are using has a medical purpose it is important that it is CE marked. There is a legal definition of a medical device but here are some practical examples;

Depending on information you enter about yourself

- Those which calculate medicine doses for you to take /inject
- Those that tell you that you have a medical condition or disease or give you an individual percentage risk score of having one.

Before you choose a medical device app - is it the right app for me?

You should think about what you will do with the results and the information that the app is giving you. If the app is giving you significant health information then be sure you will understand the result and you know what you need to do when you get the result. When an app developer applies a 'CE mark' they are claiming that the app is fit for the purpose it claims and it is acceptably safe to use. The CE mark should be visible on the app when you are looking at it in the app store or on the further information or 'landing' page. This information should also tell you what the app can be used for and how to use it.

If you can't see these details or are unsure we suggest you contact the developer to ask and in the meantime that you don't use it. **Please use only medical device apps that are CE marked.** If you see a medical device app that does not have a CE mark, then you can report it to MHRA.

Once you have started using the medical device app

Once you are sure the app is right for you and it is CE marked then you should follow the instructions carefully. Be honest with the information you put into the app. If you enter wrong information about yourself, the app may not give you the right result.

Ensure that you always update the app to the newest compatible version.

After using the medical device app

If you are in doubt about the information that the app has given you or you are concerned about your health then you should consult a healthcare professional (a pharmacist, health visitor, practice nurse or GP)

If you have any problems with the app not working as stated e.g.

- If the instructions aren't clear or the app is difficult to use
- If the app isn't giving you the results that you expected
- If you have concerns over the safety of the app or the information that it provides

Tell the MHRA about these problems. You can do this by going to our reporting page on the website https://yellowcard.mhra.gov.uk/).

You should also contact the developer/owner of the app to tell them.

Yellow Card

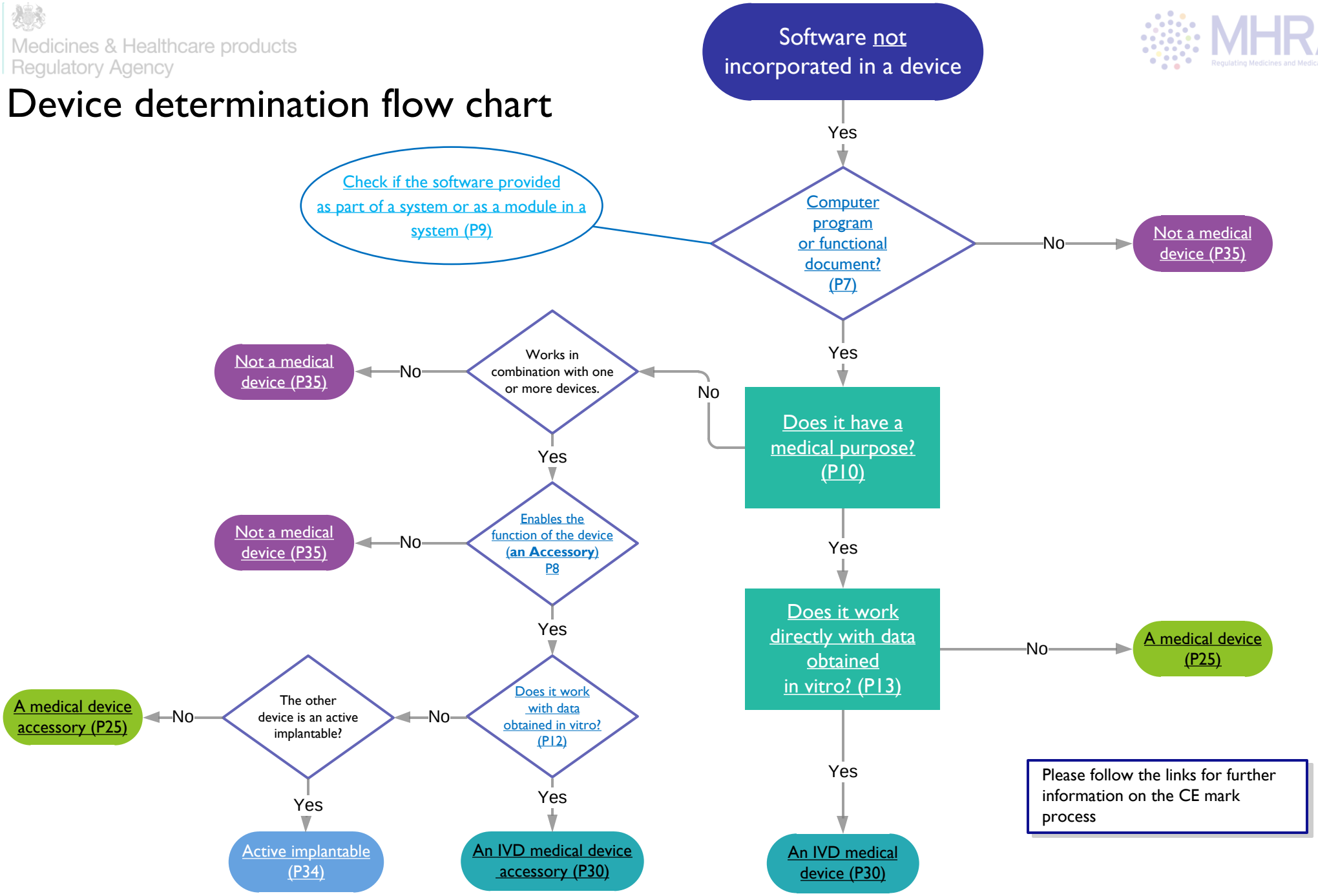
Personal data and security

It is very important that you have read the small print to understand what personal data you may have agreed to share with the developer by signing up to the app and how they might store or use your data or share your information with third parties. This includes information about you such as your name, address, date of birth and information about your health.

Additional sources of information:

RCP guidance on medical Apps: https://www.rcplondon.ac.uk/guidelines-policy/using-apps-clinical-practice-guidance

Device determination flow chart



Definitions

Computer program
"syntactic unit that conforms to the rules of a particular programming language and that is composed of declarations and statements or instructions needed to solve a certain function, task, or problem"
ISO/IEC 2382:2015(en)

MEDDEV 2.1/6 - 2016
"software" is defined as a set of instructions that processes input data and creates output data.

This includes:

- Un-compiled software - if all of the information is provided to install the software then the MDD may apply.
- Freeware / open-source software

Note
The regulations apply to all methods of software distribution. It applies to products that have been "placed on the market" rather than sold.

Interpretative document of the commission's services placing on the market of medical devices:
"'placing on the market' shall mean the first **making available** of a product on the Community market"

"'making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge"

Functional document
Software that requires separate software to perform its function. Often this will be a general purpose application.

Examples include:

- A pdf that reproduces a treatment decision flow chart with logical links.
- Spread sheets - particularly if they provide complex functionality that is beyond that of existing paper charts e.g. an excel spreadsheet that calculates Glomerular filtration rate.
- Documents with macro or script enabled functions - complex medical applications can be written with languages such as visual basic
- Interactive web pages - these can utilise programing languages such as JavaScript to produce medical applications.

Indicative words and phrases:

Software as a medical device
Standalone software
Medical apps

Accessories

An accessory is a product intended to enable a medical device to fulfil its intended function and it will be treated as a device within the relevant directive.

E.g. Software on a mobile device linked wirelessly to a monitoring device to record data.

Please Note:

Apps acting as accessories to physical medical devices such as in the measurement of temperature, heart rate, blood pressure and blood sugars could be a medical device as are programmers for prosthetics and active implanted devices.

If an app is the only way of interacting with a physical device then it may be considered to be a component of the device e.g a physical clinical thermometer with no display that links to an app on a mobile device by wireless link. The app displays, stores and analyses the data.

MEDDEV 2. 1/1
"The definition of "accessory" requires that the accessory is specifically intended by the manufacturer of the accessory to be used together with a device. The intended use of the accessory must be such as to enable a device to be used in accordance with its intended use. Therefore a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices."

Indicative words and phrases:

Can be used with..
Helps...

Systems and modules

Systems

Medical devices

There is no definition of a 'system' in the medical device directives but there are specific requirements for products placed on the market **together** that combine CE marked devices and non-CE marked products.

e.g. a combination of laptop (not a medical device), software (a medical device) and heart monitoring hardware (an accessory) is considered to be a 'system' if these are placed on the market together.

In-vitro diagnostic medical devices

Where the software is provided as part of an IVD system (or IVD kit) it should be treated as an IVDMD.

MEDDEV 2.14/1 revision 2
"a 'kit' consists of more than one component that are made available together and intended to be used to perform a specific IVD examination."

Modules

In complex systems it may be appropriate to CE mark only those functions that meet the definition of a device rather than CE marking the whole product. See section 4 of MEDDEV 2.1/6

Examples that may be devices include:

- Clinical systems that include modules that are intended to indicate the risk that a specific patient has of developing a disease based on entered data for that patient.

MEDDEV 2.1/6
"modules which are subject to the medical device Directives (Figures 1 and 2) must comply with the requirements of the medical device Directives and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices."

Medical purpose

From P6 - device decision flow diagram

Check what the **intended purpose** is (to P11).

Has one or more of these functions.

- Prevention of disease
- Diagnosis of disease, an injury or handicap
- Monitoring of disease, an injury or handicap
- Treatment or alleviation of disease, an injury or handicap
- Compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

OR

Has one of the above functions plus one of the following and looks at *in vitro* data:

- Concerning a physiological or pathological state
- Concerning a congenital abnormality
- To determine the safety and compatibility with potential recipients
- To monitor therapeutic measures

Has a medical purpose, (return to P6)

Multipurpose product

A multipurpose product, e.g. a spreadsheet program such as MS Excel, which is used occasionally in a medical environment is normally not considered to be a medical device, unless a specific medical intended purpose is assigned to it.

It **only** has one or more of these functions. *(Only proceed to this step if **all** functions on the left have been ruled out)*

- Patient medical education
- Monitors fitness/health/wellbeing
- Professional medical education
- Stores or transmits medical data without change
- Software that is used to book an appointment, request a prescription or have a virtual consultation is also unlikely to be considered a medical device if it only has an administrative function.
- Software that provides reference information to help a Healthcare Professional to use their knowledge to make a clinical decision.
- Data or databases for storing data

No medical purpose, (return to P6)

Intended purpose

A **medical purpose** is determined by what the manufacturer states in the device's labelling, instructions for use and any promotional materials.

Examples of promotional materials include:

- Adverts
- App store description and category
- The landing page
- The manufacturer's social media channels

Notes:

- Care should be taken with the description of what the software is intended to be used for. Simple changes to the description make the difference between a product being considered a device or not.
- A number of apps have a disclaimer saying "for information only" or "for research use only" or other statements that try and reduce the responsibilities of the manufacturer. However, if an app qualifies as a medical device and is placed on the market for a medical purpose will still need to comply with the relevant directive.
- General disclaimers (for example 'this product is not a medical device') are not acceptable if medical claims are made or implied elsewhere in the product labelling or associated promotional literature.
- Anecdotal quotes and testimonials are considered to be implied claims by the manufacturer if they are repeated in product literature.
- Use of a product for a medical purpose does not make it a medical device. See MHRA guidance on off-label use of a medical device.

MEDDEV 2. 1/1 1 1.1b) medical purpose

"Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose."

Indicative words and phrases:

Clinical Trials Evidence…
Clinically proven...
Medical research...

Non medical functions

Monitors fitness/health/wellbeing

The monitoring of general fitness, general health and general wellbeing is not usually considered to be a medical purpose – see monitoring.

Decision support

Software is unlikely to be a device if:

- It just reproduces a paper document in digital format. - It is down to the health care professional to make the decisions based on the advice displayed.
- It just follows the path of a procedure/treatment - there are no decisions - may provide information.
- It has decision points, options may be explained but the health care professional decides which path to take.
- It offers lifestyle treatment choices only.

Software is most likely to be a device if:

- It is linked to a specific medicine/device (is likely to be an accessory).
- It is intended to influence the actual treatment - dose, size of implant, time of treatment etc.
- It results in a diagnosis or prognosis - provides future risk of disease

Decision support software is usually considered a medical device when it applies automated reasoning such as a simple calculation, an algorithm or a more complex series of calculations. For example, dose calculations, symptom tracking, clinicians guides to help when making decisions in healthcare. This is likely to fall within the scope of the medical devices directives. Some decision support software may not be considered to be a medical device if it exists only to provide reference information to enable a healthcare professional to make a clinical decision, as they ultimately rely on their own knowledge. However, if the software/ app performs a calculation or interprets or interpolates data and the healthcare professional does not review the raw data, then this software may be considered a medical device. Apps are increasingly being used by clinicians who will rely on the outputs from this software and may not review the source/raw data.

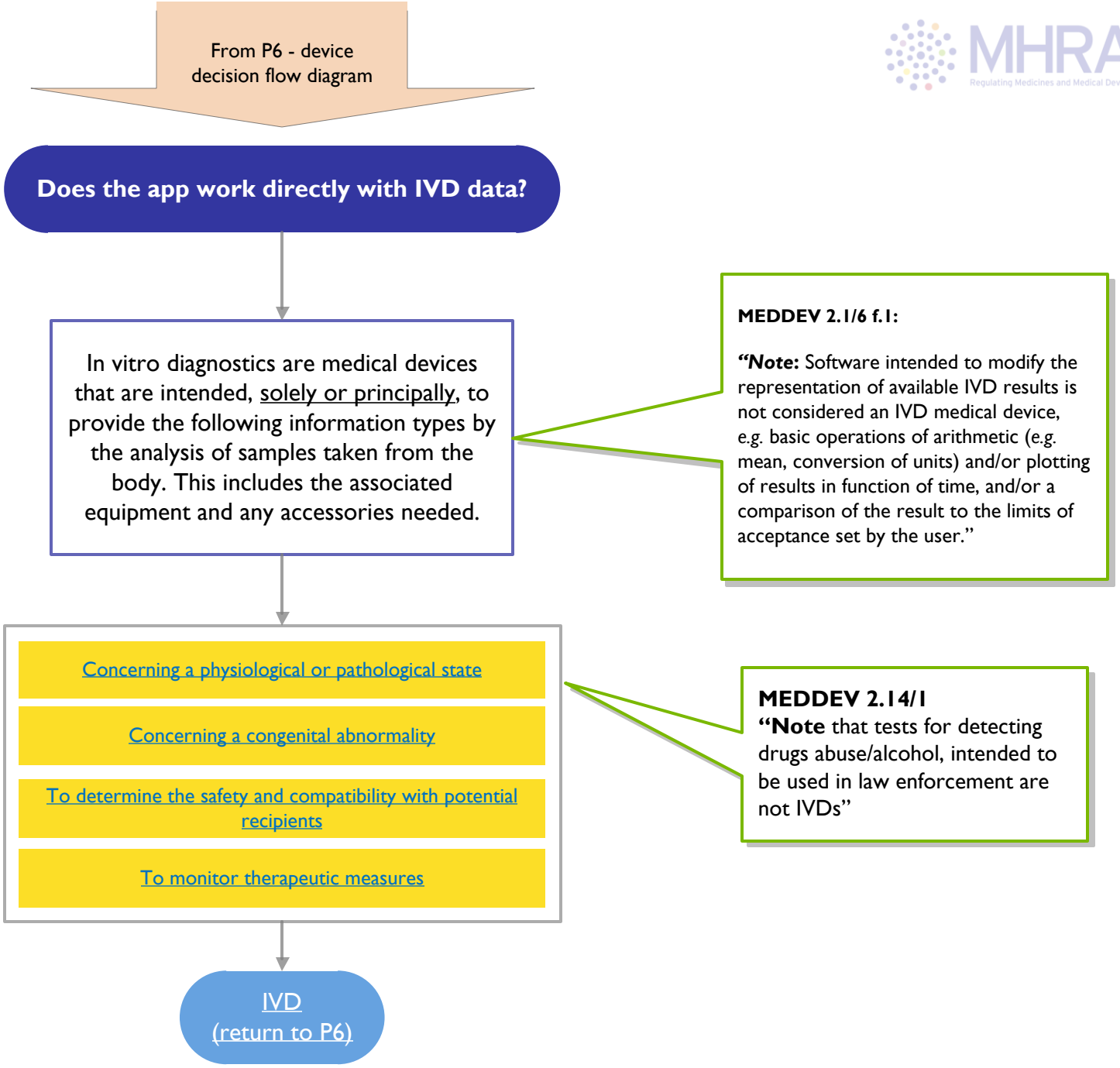
Databases

MHRA do not generally regulate data, databases or analytical services, but if you are analysing or processing data for a medical purpose, then the software that you are using may be covered by the regulations (e.g. analysing imaging or genomic data to determine treatment)

MEDDEV 2.1/6 gives examples of databases that are and are not considered to be medical devices.

Where you are using software to process or analyse data you may need to set criteria around the data that you are analysing - for example data security (hacking, integrity); ethics of data collection (informed consent etc); data quality (was the data produced within a recognised QMS, what was the performance of the test/equipment used to create the data etc)

In vitro diagnostics



Concerning a physiological or pathological state

Software that gives information about a condition or disease from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended to diagnose
- Apps and software that are intended to calculate clinical risk
- Apps and software that are intended to provide clinical decisions

Indicative words and phrases:

Marker
Prognosis
Indicates

Concerning a congenital abnormality

Software that gives information about an acquired or inherited condition or disease from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD.

Examples that may be devices include:

- Apps and software that are intended for detecting and interpreting mutations in DNA
- Apps and software that are intended for determining risk of trisomies

Indicative words and phrases:

DNA
Genomics
Data analysis
Big Data
Next Generation sequencing...

To determine the safety and compatibility with potential recipients

Software that gives information about the compatibility of blood, tissues, organs or cells donated for transplant or transfusion from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended for matching organ donors with recipients.

Indicative words and phrases:

HLA/ Human Leucocyte Antigen testing/ typing
ABO/ blood grouping
Tissue typing
Alleles
Lymphocyte cross-matching
Antigen
Antibody
Immunogenetics
Histocompatibility

To monitor therapeutic measures

Software that gives information about the presence or amount of a pharmaceutical or other therapeutic measure from results generated by an IVD. Results may be quantitative or qualitative and can be entered manually by the user or automatically from the IVD

Examples that may be devices include:

- Apps and software that are intended to provide information for the calculation of drug dose (utilising IVD data e.g. blood sugar, creatinine, genomic variant)
- Apps and software that are intended for therapeutic drug monitoring
- Apps and software that are intended to monitor blood glucose, prothrombin time or coagulation

Indicative words and phrases:

Pharmacokinetic

Prevention of disease

Prevention of disease - includes software that claims to be able to prevent specific diseases. It does not include products that claim to prevent injury or handicap.

There needs to be a link to a specific disease to qualify as a device.

Examples that may be devices include:

- Apps and software that claim that the output from the physical device can prevent disease.

Examples that are unlikely to be devices include:

- Apps and software that just provide tips or advice on prevention.

Indicative words and phrases:

Avoids...
Can benefit those who suffer from…
Combats...
Controls...
Protects against…
Stops...

Diagnosis

Diagnosis – includes devices that supply information for detecting, diagnosing as well as those that perform diagnosis independently.

This includes software that claims that the sensors from the physical device can be used for diagnosis.

Examples that may be devices include:

- Apps and software that are intended to diagnose skin cancer from an image taken by the app.
- Apps and software that are intended to make recommendation to seek further advice based on user entered data.
- Apps and software that are intended to indicate the risk that a specific patient has of developing a disease based on entered data for that patient.

Examples that are unlikely to be devices include:

- Apps and software that are intended to record images (without enhancement) of skin conditions that are then reviewed by a clinician.
- Apps and software that are intended to make general recommendations to seek further advice.
- Apps and software that are intended to indicate the risk that a specific group of the population has of developing a disease.

Indicative words and phrases:

Spots…
Detects...
Finds…
Prognosis
Screening
Symptom Checker
Triage
Risk of…
Measures...

Monitoring

Monitoring - includes devices that monitor the progress or severity of disease, an injury or handicap.

This includes software that claims that the sensors from the physical device can be used for monitoring.

There needs to be a link to a specific disease, injury or handicap.

Examples that may be devices include:

- Apps and software that are intended to allow remote access to information on physical monitors and applies user-defined filtering rules to any alarms generated by the original device.
- Apps and software that monitor a patient and collects information entered by the user, measured automatically by the app or collected by a point of care device may qualify as a medical device if the output is intended to affect the treatment of an individual.

See Borderline manual 1.17 – 9.6 Classification of software for information management and patient monitoring

Examples that are unlikely to be devices include:

- Apps and software that simply replace a written diary/log of symptoms that can be used when consulting with the patient's doctor. However, the addition of features that enhance the data presented may bring it into the remit of the directive.
- Apps and software for monitoring sport or fitness purposes, e.g. heart rate, are not considered to be medical devices. However, in some specific cases, where the intention is to investigate the physiological processes they may be.

Indicative words and phrases:

Check
Alarms

Treatment and alleviation

Treatment - includes devices that provide information that can be used to enable treatment to be performed or claim that the output from the physical device can be used to treat.

There needs to be a link to a specific disease, injury or handicap.

Alleviation - includes devices that reduce symptoms or severity of a disease, injury or handicap.

Examples that may be devices include:

- Apps and software that are intended to calculate the dose of a insulin a diabetic needs to treat their diabetes based on carbohydrate in a meal.
- Apps and software that are intended to automate the treatment pathway for an individual patient.
- Apps and software that are intended for the treatment of neurotrauma, neurodegenerative and neuropsychiatric conditions.

See Borderline manual 1.17 – 9.5

Examples that are unlikely to be devices include:

- Apps and software that are intended to treat non-medical conditions e.g non-specific stress.
- Apps and software that are intended to just provide tips or advice or link to support groups.
- Apps and software that are intended to remind users that medicines are taken.

Indicative words and phrases:

Calculates...
Can benefit those who suffer from…
Clears…
Combats…
Controls…
Counteracts…
Cure/cures…
Eliminates…
Fights…
Heals…
Help/help with…
Reduce pain

Compensation

Compensation - includes software that the manufacturer claims can compensate for an injury or handicap or claims that the sensors and output from the physical device can be used for this purpose. It doesn't include those products that are intended for general use but can be used to compensate for an injury or handicap.

There needs to be a link to a specific injury or handicap.

Examples that may be devices include:

- Apps and software that are intended to magnify text specifically for people with visual impairment.
- Apps and software that are intended to amplify sounds for people with reduced hearing.

Examples that are unlikely to be devices include:

- Apps and software that are intended to magnify text but there is no mention of visual impairment in the manufacturer's claims.
- Apps and software that are intended to amplify sounds but the manufacture's claims do not mention reduced hearing ability.

Indicative words and phrases:

Corrects
Helps

Investigation, replacement or modification

Investigation, replacement or modification of the anatomy or of a physiological process includes devices that claim to be able to investigate, replace or modify the anatomy or a physiological process.

Examples that are unlikely to be devices include:

- Educational anatomy and physiology apps and software.

Indicative words and phrases:

Control of conception

Control of conception - includes devices that claim to be directly able to make pregnancies more likely or to be able to prevent pregnancy.

MEDDEV 2.2/4 – "make pregnancies more frequent"

Examples that are unlikely to be devices include:

- Apps and software that just track or display data related to a woman's menstrual cycle to aid in ovulation prediction.
- Apps and software that just provide tips or advice.

Indicative words and phrases:

Fertility
Ovulation
Menstruation

Medical device & accessories.

For all software and apps that meet the definition of a medical device, the following guidance is given to aid some key requirements of CE marking.

For more detail see MHRA guidance:
Medical devices: conformity assessment and the CE mark

Classification
Manufacturers of 'general' medical devices will need to determine the classification of their products to determine the route to compliance, this is done by the use of the classification rules in annex IX of the directive. There are four classes as follows:

Class I - generally regarded as low risk
Class IIa - generally regarded as medium risk
Class IIb - generally regarded as medium risk
Class III - generally regarded as high risk

This guidance lists rules that are likely to apply to software and apps.

Essential requirements
The software must meet all of the general essential requirements and the relevant design and construction essential requirements contained in annex I of the directive. This guidance lists those essential requirements that are likely to apply to software and apps.

Where available, relevant harmonised standards (external link) may be used to demonstrate how many of the requirements have been met.

Post market Surveillance
Once a medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the competent authority, which is MHRA in the UK. See guidance on reporting adverse incidents for information on how to do this. This ensures the device is acceptably safe to use for as long as it is in use.

Note
Accessories are treated as if they are medical devices and all the relevant requirements will apply.

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer may wish to display the CE mark on the primary landing page.
See CE marking of general medical devices for details of the requirements for displaying the mark. Details on how to reproduce the CE mark is given here:
http://ec.europa.eu/enterprise/faq/ce-mark.htm

Classification rules

General essential requirements

Design and Construction essential requirements

Post market surveillance

In-house manufacture
Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:
In-house manufacture of medical devices

Manufacturers must also consider the requirements of the Data Protection and e-Privacy Directives. ICO's Privacy in mobile apps guidance may be helpful.

Medical device classification

Advice on classification is given for general medical devices but for software, an active device, the following existing classification rules are most applicable:

- Implementing rule 2.3 - Software, which drives a device or influences the use of a device automatically falls into the classification of that device.

Software that directly modifies the state/action/use of another device is considered to be driving that device.

Software which produces data that is intended to be manually fed into a device, thereby modifying the state/action/use of the device, is considered to be influencing that device.

- Rule 9 - Active therapeutical devices are generally class IIa - however if potentially hazardous then class IIb.

MDD
Active therapeutical device:
"Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap."

- Rule 10 - Active devices intended for diagnosis are generally class IIa - however if potentially hazardous then class IIb.

MDD:
Active device for diagnosis:
"Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities."

- Rule 12 - All other active devices are class I.

- Rule 14 - All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in class IIb.

While compliance of class I devices is based on self-declaration by the manufacturer, all other devices require use of a notified body to assess compliance.
UK manufacturers of class I devices, must also register with MHRA.

Clinical data is required for all medical devices and for some novel software clinical investigations may be needed.

For general advice on classification see MEDDEV 2. 4/1 Rev. 9 June 2010 - Classification of medical devices.

Medical device essential requirements - general

The following apply to all devices:

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

> The benefits of your app need to outweigh any risks from use of the app.

This shall include:

- reducing as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

> The user interface needs to be consistent, graphics and text need to be clear and readable.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

> Your app needs to be designed with safety in mind. You should initially aim to design out risks.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

> You need to have the evidence that the app does what you say it does. This may be gathered through clinical evaluation.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

> 6a You must perform a clinical evaluation of your app. See MEDDEV 2.7/1 Clinical evaluation: Guide for manufacturers and notified bodies

Design and construction essential requirements

The manufacturer will need to determine which apply to their software by reviewing the details in Annex I of the MDD. The following are likely to apply to software devices:

9.1. If the device is intended for use in combination with other devices **or equipment**, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

12.9.1. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

This information comprises the details on the label and the data in the instructions for use.

13.6. Where appropriate, the instructions for use must contain the following particulars:

(c) if the device must be installed with or connected to other medical devices **or equipment** in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;

d) all the information needed to verify whether the **device is properly installed** and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;

The following are possibly applicable to software devices:

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.

The MDD requires the whole system to be safe. This is particularly pertinent to stand alone software, where the manufacturer must demonstrate compatibility with the recommended hardware platforms.

Validation of your app is a requirement before placing on the market.

The instructions should contain all the information needed to verify whether the device is properly installed and can operate correctly and safely. These can be provided in electronic form if they are packaged with the software and the risk of doing so is less than providing IFU in paper form. These are not needed for Class I and IIa devices if they can be used safely without any such instructions.

This may include details of validated operating systems, hardware and other running software such as anti virus.

i.e. metric units.

Medical device post market surveillance.

Manufacturers have a responsibility to implement an effective post-market surveillance system to ensure that any problems or risks associated with the use of their device once freely marketed are identified early, reported to competent authorities, and acted upon. This is known as the medical devices vigilance system.

For software, a system of registration / activation may aid the manufacturer trace devices that have been distributed by third party distributors or by app stores. This is important when undertaking any field safety corrective action.

Adverse Incident Reporting

Manufacturers should follow the guidance for reporting adverse incidents and field safety corrective actions to MHRA.

MHRA MORE: Manufacturers' Online Reporting Environment

Manufacturers are encouraged to use the Manufacturer's On-line Reporting Environment to submit Vigilance reports to the Agency

In vitro diagnostic medical devices & accessories.

For all software and apps that meet the definition of an in-vitro diagnostic medical device, the following guidance is given to aid some key requirements of CE marking.

For more detail see MHRA guidance:
In vitro diagnostic medical devices: guidance on legislation

Categories
Manufacturers of in-vitro diagnostic medical devices will need to determine which category of product the software is to determine the route to compliance. There are four categories as follows:

general IVDs
IVDs for self-testing
IVDs in Annex II List B of the directive:
IVDs in Annex II List A of the directive:

Essential requirements
The software must meet all of the general essential requirements and the relevant design and manufacturing requirements contained in annex I of the directive. This guidance lists those essential requirements that are likely to apply to software and apps.

Where available, relevant harmonised standards (external link) may be used to demonstrate how many of the requirements have been met.

Post market Surveillance
Once an in-vitro diagnostic medical device has been placed in the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the competent authority, which is MHRA in the UK. See guidance on reporting adverse incidents for information on how to do this. This ensures the device is acceptably safe to use for as long as it is in use.

Note
Accessories are treated as if they are medical devices and all the relevant requirements will apply.

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer may wish to display the CE mark on the primary landing page.
See CE marking of in vitro diagnostic medical devices for details of the requirements for displaying the mark. Details on how to reproduce the CE mark is given here:
http://ec.europa.eu/enterprise/faq/ce-mark.htm

Essential requirements

Design and Manufacturing requirements.

Post market surveillance

In-house manufacture
Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:
In vitro diagnostic medical devices: guidance on legislation

Manufacturers must also consider the requirements of the Data Protection and e-Privacy Directives. ICO's Privacy in mobile apps guidance may be helpful.

IVD essential requirements - general

The following apply to all devices:

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise, directly or indirectly, the clinical condition or the safety of the patients, the safety or health of users or, where applicable, other persons, or the safety of property. Any risks which may be associated with their use must be acceptable when weighed against the benefits to the patient and be compatible with a high level of protection of health and safety.

The benefits of your app need to outweigh any risks from use of the app.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

Your app needs to be designed with safety in mind. You should initially aim to design out risks.

3. The devices must be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 1(2)(b), as specified by the manufacturer, taking account of the generally acknowledged state of the art. They must achieve the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.
The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.

You need to have the evidence that the app does what you say it does.

4. The characteristics and performances referred to in sections 1 and 3 must not be adversely affected to such a degree that the health or the safety of the patient or the user and, where applicable, of other persons, are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport
conditions (temperature, humidity, etc.) taking account of the instructions and information provided by the manufacturer.

IVD design and manufacturing requirements.

In addition to the general requirements there are a series of specific design and manufacturing requirements. The manufacturer will need to determine which apply to their software by reviewing the details in Annex I of the IVDMDD.

1. Chemical and physical properties
2. Infection and microbial contamination
3. Manufacturing and environmental properties
4. Devices which are instruments or apparatus with a measuring Function
5. Protection against radiation
6. Requirements for medical devices connected to or equipped with an energy source
7. Requirements for devices for self-testing
8. Information supplied by the manufacturer

IVD medical device post market surveillance.

Manufacturers have a responsibility to implement an effective post-market surveillance system to ensure that any problems or risks associated with the use of their device once freely marketed are identified early, reported to competent authorities, and acted upon. This is known as the medical devices vigilance system.

For software, a system of registration / activation may aid the manufacturer trace devices that have been distributed by third party distributors or by app stores. This is important when undertaking any field safety corrective action.

Adverse Incident Reporting

Manufacturers should follow the guidance for reporting adverse incidents and field safety corrective actions to MHRA.

MHRA MORE: Manufacturers' Online Reporting Environment

Manufacturers are encouraged to use the Manufacturer's On-line Reporting Environment to submit Vigilance reports to the Agency

Active implantable medical device & accessories.

Accessory software for an Active implantable Medical device should be treated as an Active implantable Medical device. Further guidance is provided in European guidance MEDDEV 2. 1/2 rev 2.

A prospective buyer should be able to identify that the app meets the relevant essential requirements prior to purchase. As such, a developer may wish to display the CE mark on the primary landing page. See CE marking of active implantable medical devices for details of the requirements for displaying the mark. Details on how to reproduce the CE mark is given here:
http://ec.europa.eu/enterprise/faq/ce-mark.htm

In-house manufacture
Certain requirements don't apply if your device is only being used for patients within the institute it was made. See:
In-house manufacture of medical devices

Manufacturers must also consider the requirements of the Data Protection and e-Privacy Directives. ICO's Privacy in mobile apps guidance may be helpful.

Not a medical device

Those apps that are not medical devices may be considered to be mHealth products. Work is ongoing at European level to determine a suitable legal framework.
http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth

The commission has also published a non-exhaustive description of EU legislation, applicable to lifestyle and wellbeing apps:
https://ec.europa.eu/digital-single-market/news/commission-staff-working-document-existing-eu-legal-framework-applicable-lifestyle-and

Privacy Code of Conduct for mHealth apps and draft mHealth assessment guidelines are available here:
https://ec.europa.eu/digital-single-market/en/news/current-initiatives-unlock-potential-mobile-health-europe

Other UK legislation may apply such as the General Product Safety Regulations:

https://www.gov.uk/product-safety-for-manufacturers

https://www.gov.uk/product-liability-and-safety-law

Manufacturers must also consider the requirements of the Data Protection and e-Privacy Directives. ICO's Privacy in mobile apps guidance may be helpful.

References

The following documents provide useful information to help software developers understand regulations for medical device software:

- European Commission MEDDEV 2.1/1 Definitions of "medical devices", "accessory" and "manufacturer"
- European Commission Manual on borderline and classification in the Community Regulatory framework for medical devices
- Team NB FAQ on Implementation of EN 62304:2006 with respect to MDD 93/42/EEC.
- MHRA Borderlines with medical devices

Standards

EN 62366 - Medical devices - Application of usability engineering to medical devices
EN 62304 - Medical device software -- Software life cycle processes
EN ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971 - Medical devices. Application of risk management to medical devices
BSI PAS 277: 2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice
PD IEC/TR 80002-1 - Medical device software Part 1: Guidance on the application of ISO 14971 to medical device software

Other national / international guidance (in English)

Sweden: Guidance for qualification and classification of Medical Information Systems.
Germany: Guidance on "Medical Apps"
IMDRF: Software as a Medical Device (SaMD): Key Definitions

Revision history

Version	Date	Changes
1.02	Oct-16	Format background colour of examples Change words and phrases boxes Clarification on P10 & 12 - decision support
1.01	Sep-16	Link (P1) and YellowCard graphic updated
1.00	Aug-16	First edition