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Study on Safety of non-embedded software; Service, data access, and legal issues of advanced robots, autonomous, connected, and AI-based vehicles and systems

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Final Study Report regarding Safety of health, lifestyle and wellbeing apps

A study prepared for the European Commission
DG Communications Networks, Content & Technology
by:

TNO innovation for life

VVA CONSULTING

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Digital Single Market

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Abstract (EN)

The main objective of the study is a fact finding mission on safety incidents with health, lifestyle and wellbeing apps and the legal framework that covers these incidents. Based on desk research, confirmed via stakeholder consultation and a workshop, it is concluded that presently it is unclear whether and what European legislation covers the safety of health, lifestyle and wellbeing apps. Notwithstanding the lack of reported incidents at this point in time, many of the eight Member States studied as part of the project are fully aware of the need to offer some kind of transparency with regard to the safety of health, lifestyle and wellbeing apps to the public at large. The investigation showed that many countries undertake activities to help citizens in assessing the relevance, adequacy and effectiveness of health, lifestyle and wellbeing apps. No general framework to do so is yet in place, though many guidelines that are produced focus on a similar set of activities: medical content, security and privacy, usability, effectiveness. International and European standardisation efforts are under way as well, but these are still far from a conclusive phase.

Abstract (FR)

L'objectif principal de l'étude est tout d'abord une enquête sur les incidents liés à la sécurité dans le cadre des applications de santé, de style de vie et de bien-être ainsi qu'une analyse du cadre juridique qui couvre ces incidents. Basé sur une vaste recherche documentaire, qui a été par la suite confirmée par une consultation des parties prenantes et un séminaire organisé par le consortium, il est conclu qu'actuellement il n'est pas clair si et qu'est-ce que la législation européenne couvre en termes de sécurité des apps de santé, de mode de vie et de bien-être. Nonobstant l'absence d'incidents signalés à présent, un bon nombre parmi les huit États membres étudiés dans le cadre du projet sont pleinement conscients de la nécessité d'offrir une certaine transparence en ce qui concerne la sécurité des applications de santé, de vie et de bien-être au public en général. L'enquête a montré que de nombreux pays entreprennent des activités pour aider les citoyens à évaluer la pertinence, l'adéquation et l'efficacité des applications de santé, de mode de vie et de bien-être. Aucun cadre général n'est encore en place, bien que de nombreuses lignes directrices sont produites et se concentrent sur un ensemble similaire d'activités : le contenu médical, la sécurité et la vie privée, la facilité d'utilisation ainsi que l'efficacité. Des efforts de normalisation internationaux et européens sont également en cours, mais ils sont encore loin d'être définitifs.

Executive Summary (EN)

The European Commission commissioned a 'Study on Safety of non-embedded software; Service, data access, and legal issues of advanced robots, autonomous, connected, and AI-based vehicles and systems' (SMART 2016/0071). Part of this study was a fact finding mission on safety incidents with health, lifestyle and wellbeing apps. This study encompassed desk research, interviews and a workshop.

The overall conclusion on the basis of this fact finding is that at present no safety incidents concerning non-embedded software, in particular in this study of health, lifestyle and wellbeing apps that do not fall under the Medical devices legislation can be found in public sources.

This however does not mean that safety incidents with health, lifestyle and wellbeing apps do not exist. A number of reasons for underreporting can be identified:

- users who experience a safety incident, do not relate this incident to the use of the app;
- users who experience a safety incident, do not know where and how to report this safety incident;
- medical professionals that are confronted with safety incidents of non-medical devices (devices that do not fall under Medical Devices legislation) do not know where to report these incidents;
- no public authority exists that is responsible for registering and surveying for safety incidents of health, lifestyle and wellbeing apps; these incidents thus are not on the radar of potentially relevant public authorities.

The study checked for relevant legislation applicable to safety incidents of health, lifestyle and wellbeing apps. For some legislation, such as the General Product Safety Directive and the Product Liability Directive, it is currently unclear if and to what extent they can be applied to health, lifestyle and wellbeing apps. Other forms of legislation are relevant for non-embedded software but do not relate to covering incidents (such as the Consumer Rights Directive and the Unfair Commercial Practices Directive). The Radio Equipment Directive (RED) covers non-embedded software and needs to be taken into account. The main conclusion here is that at present it is unclear whether and what European legislation covers the safety of health, lifestyle and wellbeing apps. The RED covers part of the safety and may help securing safety of health,lifestyle and wellbeing apps.

Based on an investigation in eight European Member States - Austria, France, Germany, Italy, the Netherlands, Spain, Sweden and the United Kingdom - it can be concluded that many countries undertake activities to help citizens in assessing the relevance, adequacy and effectiveness of health, lifestyle and wellbeing apps. No general framework to do so is yet in place, though many guidelines that are produced focus on a similar set of activities: medical content, security and privacy, usability, effectiveness. Medical content relates to the reliability of the information provided, without the requirement of clinical evidence (though some guidelines refer to clinical evidence as potential basis).

Effectiveness is also hard to evaluate, given the lack of formal and enforceable guidelines in practice. For many countries, medical professional organisations and medical quality assurance organisations (BSI, GGD, etc.) have the lead in these initiatives. Next to this, the CEN has formally agreed to start a working group under TC251 that will address the safety of health, lifestyle and wellbeing apps. This initiative uses an earlier initiative of the

UK BSI that resulted in a document of guidelines for the design of health, lifestyle and wellbeing apps (PAS277).

The overall conclusion is that, notwithstanding the lack of reported incidents at this point in time, many countries are fully aware of the need to offer some kind of transparency with regard to the safety of health, lifestyle and wellbeing apps to the public at large. Especially medical professional organisations and public organisations active in assuring quality of health care, develop activities to help controlling the safety of health, lifestyle and wellbeing apps. The initiative, started by CEN will also be of help in preventing potential safety incidents of health, lifestyle and wellbeing apps, while assuring the quality of these apps given the purposes they serve.

Executive Summary (FR)

La Commission européenne a demandé une "Etude sur la sécurité des logiciels non-intégrés; le service, l'accès aux données et les questions juridiques des robots, des véhicules et des systèmes autonomes, connectés et basés sur l'intelligence artificielle (SMART Number 2016/0071)". Une partie de cette étude a été une enquête sur les incidents liés à la sécurité dans le cadre des applications de santé, de style de vie et de bien-être. Cette étude comprenait des recherches documentaires, des entretiens et l'organisation d'un séminaire.

La conclusion générale sur la base de cette enquête est qu'à l'heure actuelle aucun incident liés à la sécurité des logiciels non intégrés, en particulier dans cette Etude les applications de santé, de mode de vie et de bien-être, qui n'entrent pas dans le champ de la directive relative aux dispositifs médicaux, peut être trouvé dans des sources publiques.

Cependant, cela ne signifie pas que les incidents liés à la sécurité des applications de santé, de style de vie et de bien-être n'existent pas. Un certain nombre de raisons expliquant l'absence de signalement des incidents peuvent être identifiées :

- les utilisateurs qui subissent un incident liés à la sécurité, ne peuvent pas relier cet incident à l'utilisation d'une l'application;
- les utilisateurs qui subissent un incident liés à la sécurité, ne savent pas où et comment signaler cet incident;
- le personnel médical qui est confronté à des incidents liés à la sécurité des dispositifs non médicaux (dispositifs qui ne relèvent pas de la directive relative aux dispositifs médicaux) ne sait pas où signaler ces incidents;
- il n'existe pas d'autorité publique chargée de l'enregistrement et de la surveillance des applications de santé, de mode de vie et de bien-être pour les incidents; ces incidents ne sont donc pas sur le radar des autorités publiques concernées.

L'étude a examiné la législation pertinente applicable aux incidents liés à la sécurité des apps de santé, de mode de vie et de bien-être. Pour certaines législations, telles que la directive relative à la sécurité générale des produits et la directive en matière de responsabilité du fait des produits défectueux, il est actuellement flou si et dans quelle mesure elles peuvent être appliquées aux applications de santé, de mode de vie et de bien-être. D'autres formes de législation semblent pertinentes pour les logiciels non-intégrés mais ils ne concernent pas les incidents (tels que la directive relative aux droits des consommateurs et la directive relative aux pratiques commerciales déloyales des entreprises vis-à-vis des consommateurs dans le marché intérieur). La directive sur le marché d'équipements radioélectriques couvre les logiciels non intégrés et doit être prise en compte. La principale conclusion est qu'à l'heure actuelle, il n'est pas clair si et quelle

législation européenne couvre la sécurité des applications de santé, de style de vie et de bien-être. La directive sur le marché d'équipements radioélectriques couvre quand même une partie de la sécurité et peut donc aider à assurer la sécurité des applications de santé, de style de vie et de bien-être.

Sur la base d'une enquête menée dans huit États membres européens-l ‘Autriche, la France, l'Allemagne, l'Italie, les Pays-bas, l'Espagne, la Suède et le Royaume-Uni-, on peut conclure que de nombreux pays entreprennent des activités pour aider les citoyens à évaluer la pertinence, l'adéquation et l'efficacité des apps de santé, de mode de vie et de bien-être. Aucun cadre général n'est encore en place, bien que de nombreuses lignes directrices sont mis en place et se concentrent sur un ensemble similaire d’activités : le contenu médical, la sécurité et la vie privée, la facilité d’utilisation, ainsi que l'efficacité. Le contenu médical se rapporte à la fiabilité de l'information fournie, sans l'exigence de preuves cliniques (bien que certaines lignes directrices se rapportent à la preuve clinique comme base potentielle).

L'efficacité est également difficile à évaluer, étant donné l'absence de directives formelles et exécutoires dans la pratique. Pour de nombreux pays, les organisations professionnelles médicales et les organisations médicales d'assurance (BSI, GGD, etc.) ont le rôle principal dans ces initiatives. À côté de cela, le CEN a officiellement accepté de lancer un groupe de travail sous TC251 qui traitera de la sécurité des applications de santé, de style de vie et de bien-être. Cette initiative utilise une initiative antérieure du BSI britannique qui a abouti à un document de lignes directrices pour la conception des applications de santé, de style de vie et de bien-être (PAS277).

La conclusion générale est que, malgré l'absence d'incidents signalés à ce stade, de nombreux pays sont pleinement conscients de la nécessité d'offrir une sorte de transparence en ce qui concerne la sécurité des applications de santé, de style de vie et de bien-être au grand public. En particulier les organisations professionnelles médicales et les organisations publiques responsables d’assurer la qualité développent des activités pour aider à contrôler la sécurité des applications de santé, de style de vie et de bien-être. L'initiative, lancée par le CEN, aidera également à prévenir les incidents potentiels causés par des applications de santé de mode de vie et de bien-être, tout en assurant la qualité de ces applications, compte tenu des buts qu'ils servent.

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List of abbreviations

Abbreviation	Full name
DG CONNECT	Directorate General for Communications Networks, Content & Technology
GPSD	General Product Safety Directive
MD	Medical Devices
MDD	Medical Devices Directive
MDR	Medical devices regulation (2017/745/EC)
PLD	Product Liability Directive
RED	Radio Equipment Directive

1. INTRODUCTION

Task 1 of the SMART 2016/0071 study is a fact finding task. It focuses on inventorying incidents with non-embedded software in the domain of health, lifestyle and wellbeing that do not fall under the Medical Device legislation.[1] In addition, it provides an overview of regulatory activities dealing with safety of non-embedded software related to health, lifestyle and wellbeing (that do not fall under the MDR) in eight Member States. The eight countries that are covered are, in alphabetical order: Austria (AU), France (FR), Germany (GE), Italy (IT), The Netherlands (NL), Spain (ES), Sweden (SW) and the United Kingdom (UK).

The focus of this task is on safety, "understood as freedom from unacceptable danger, risk or harm, including security vulnerabilities".[2] As will be discussed in chapter 3, one issue to clarify is what typical causes can be identified that may lead to unacceptable danger, risks and harm in the case of health, lifestyle and wellbeing apps.

Having presented the research methodology in this chapter, chapter 2 presents a number of crucial concepts for this study. Subsequently, attention is paid to the concept 'safety' (section 2.1), the concept 'a (serious) incident' (section 2.2), the concept 'non-embedded software' (section 2.3), the concept 'safety of health, lifestyle and wellbeing apps' (section 2.4) and 'measures to offer safety guidelines' (section 2.4).

The focus in Chapter 3 is on non-embedded software related to health, lifestyle and wellbeing that do not fall under the MDR. First, the MDR will be introduced and briefly discussed (section 3.1). This is relevant given the role of the MDR in scoping the work of regulatory agencies in the various countries we studied. Second, the concept of non-embedded software related to health, lifestyle and wellbeing is discussed (section 3.2). Special attention is given to examples that highlight the 'grey zone' between medical devices and non-medical devices.

Chapter 4 presents the results of the study on incidents related to health, lifestyle and wellbeing applications. We will present the method used, followed by the results obtained. The chapter ends with a discussion of the results obtained.

Chapter 5 presents the results of the analysis of Member State activities in dealing with non-embedded software in health, lifestyle and wellbeing that do not fall under the MDR. The countries will be alphabetically presented, followed by first order analysis of the findings of the countries in the light of the delineations that have been made in the former sections

The report will conclude with a brief overview of the main results.

1.1. Research methodology

[1] At present, the Medical Devices Directive (93/42/EEC) is applicable. From April 5, 2020 onwards, the Directive will be repealed and replaced by the Medical Devices Regulation (2017/745/EC). The main differences between the Directive and the Regulation can be found at https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en (last accessed May 31, 2018). In the report we will use MD legislation and MDR interchangeably, referring to the same legislative framework.

[2] See Tender Specifications, SMART 2016/0071, p. 3 footnote 4.

This report is aimed at exploring recent incidents and accidents regarding health, lifestyle and wellbeing apps and to find out if and how Member States are responding to these. In order to inventory the activities undertaken by the Member States, we have established a list of experts. Experts have been approached by mail and by phone. The branch organisation The App Association (ACT) offered assistance by sending out a brief survey to their members. The experts we have talked to come from industry, government and academia. Parallel to approaching experts, we have performed desk research, looking into recent EU- and MS-specific reports and projects dealing with safety in relation to non-embedded software.

Concerning the inventory of incidents, we have checked for public manifestations of incidents with health, lifestyle and wellbeing applications that do not fall under the MD legislation. Incidents should be attributable to a safety failure of a health, lifestyle and wellbeing application. Failures in the use of the application, for instance because data presented by the app are misinterpreted, are out of scope of the study. We checked the internet using a combination of keywords on presence of incidents. Section 4.1 presents the result of this search.

We subsequently performed an analysis of case law in four countries: France, Italy, the Netherlands and Spain. Section 4.2 details the findings of this analysis. Section 4.3 discusses the limitations to the empirical findings on the basis of a more detailed conceptual deconstruction of the safety of non-embedded software health, lifestyle and wellbeing apps.

For chapter 5 (regulatory initiatives by Member States), we collected material through desk research and by requesting contact persons for either material or other contact persons we could approach. Documentation provided by the Contractor was also used to distil additional material and initiatives on Member State level. The materials found created a sufficiently rich and coherent picture that we are confident not to have missed relevant initiatives.

The workshop that was held April 19th 2018 in Brussels helped validating and enriching our findings. Validation occurred through presentation and discussion of our findings in a number of sessions. The discussion by the participants and the presentation and subsequent discussion of a number of perspectives by invited guest speakers enriched the findings. The workshop was visited by 34 participants, of which seven were from Commission's services, four were from the project team, and three were invited speakers. The 20 remaining participants came from industry, NGOs and public organisations.

Notwithstanding the breadth of the research approach chosen, we want to make a few remarks concerning some limitations we experienced during the research:

- Access to expertise on legal and regulatory issues in each Member State. We have tried to gather expertise on legal and regulatory issues through our network and contacts; this turned out to be challenging. Because we focus on health, lifestyle and wellbeing applications that do not fall under the MDR, it showed to be difficult to locate experts that were especially able to cover regulatory issues dealing with safety issues of devices that do not fall under the MD legislation.
- Terminology and scoping. No standard terminology is yet present in case of health, lifestyle and wellbeing apps describing safety and risk issues. The description of non-embedded software as presented in the Tender opens up a broad interpretation that needs to be confined in order to make it useful for the study (see section 2.3). In a

similar manner we had to clarify the notion of safety on the basis of the description presented in the Tender Specifications (see 2.1).

2. CONCEPTUAL FRAMEWORK OF THE STUDY

The objective of the study is to inventory safety incidents with health, lifestyle and wellbeing apps. Relevant concepts for this study are outlined in the following sections.

2.1. Safety as a concept

In the document that was used for the public consultation on the safety of apps and other non-embedded software, the European Commission describes safety as the "freedom from unacceptable danger, risk or harm including security vulnerabilities ("cyber-security") and cover[ing] physical, economic as well as non-material damage."[3] This description slightly differs from the definition as posed in the Tender Specifications and includes danger, risk or harm. While the description served mainly the purpose of feeding the public consultation, the use of the concepts danger, harm and risk helps understanding the manner in which safety incidents may manifest themselves. We interpret harm as the manifestation of physical, economic or non-material damage.[4] Risk and danger refer to the probability that harm may be caused. The description of safety as put forward in the consultation document refers to a level of harm that should not be trespassed (going beyond a danger, risk or harm being acceptable) in order for a health, wellbeing or lifestyle app to remain acceptable.

Two schemes might help in understanding when a danger, risk or harm should be considered unacceptable: the medical devices legislation and the legislation related to product safety. Both schemes deal with products. Their applicability for apps needs to be demonstrated, but still they might offer insight in how to approach the demarcation between acceptable and unacceptable danger, risk or harm.

For medical devices, this demarcation is associated with risk classes (see below).

For products, the General Product Safety Directive (2001/95/EC) may offer guidance. The GPSD defines a 'safe product' as a product that under normal foreseeable conditions of use poses limited and acceptable risks. If the GPSD definition were applied, that would imply that health, lifestyle and wellbeing apps are 'safe' when the apps pose limited and acceptable risks as long as these apps are used under normal foreseeable conditions. This definition of 'safety' differs from the description of safety presented above. Key to the notion of safety in the GPSD is the foreseeable use.[5]

We thus need to clarify whether the GPSD applies to health, lifestyle and wellbeing apps. The GPSD is applicable to products. The GPSD itself does not provide for a conclusive definition on the concept 'product'. An app is composed of a set of algorithmic procedures

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[3] Synopsis report of the public consultation on the safety of apps and other non-embedded software; downloadable from https://ec.europa.eu/digital-single-market/en/news/summary-report-public-consultation-safety-apps-and-other-non-embedded-software

[4] See https://www.collinsdictionary.com/dictionary/english/harm, that also hints at purposeful causation of harm.

[5] This notion of foreseeable use is also present in a recently published Staff Working Document on liability of emerging digital technologies. This Staff Working Document presents an updated discussion on the liability of defective products, with a focus on emerging digital technologies. The Staff Working Document acknowledges the problematic status of devices that may be embedded with software that was not originally placed on the device and that may cause safety incidents. It however does not offer a conclusive point of view with respect to the legislative approach that could be applied to these safety incidents but recommends further investigation of this issue. Commission Staff Working Document (2018). Liability for emerging digital technologies. SWD (2018) 137, final.

that make use of data delivered to the algorithms and that function on a device of which it uses functionalities as well (such as how data are collected, stored and disseminated and additional functionality such as identity and authentication mechanisms). The Commission warns in a Staff Working Document on Lifestyle and Wellbeing apps on the applicability of the GPSD for these apps.[6] It states: "Due to the fact that both the General Products Safety Directive and the Directive on liability for defective products apply to manufactured products, it is not yet clear if and to what extent they apply to lifestyle and wellbeing apps."[7] Notwithstanding the as yet uncertain position with respect to the applicability of the GPSD to health, lifestyle and wellbeing apps, in the case that GPSD would apply, the software of the app will need to be designed such that foreseeable use can be derived from it, for instance through functional and technical specifications and testing procedures.

The safety of radio equipment, when placed on the market, is governed by the Radio Equipment Directive 2014/53/EU (RED). Radio equipment is defined in Article 2 of that Directive and clarifications are given in the recent RED Guide published on the Commission website.[8] Safety in this Directive refers to the proper functioning of the product that makes use of radio equipment for connectivity and for software uploads. Malfunctioning of the radio equipment may lead to distorted functionality of the device and/or compromised uploading of software.

The RED conferred on the Commission empowerments in its Article 3(3)(i) to ensure that the overall compliance of the equipment at the upload of new software is not compromised. Additional empowerments were conferred in Article 4 which has provisions for software manufacturers intended to be uploaded into radio equipment.

The Green Paper on Mobile Health does not offer guidance on the concept of safety for health, lifestyle and wellbeing apps. It raises as a topic for study the need to investigate whether European legislation is apt to cope with the safety of lifestyle and wellbeing apps[9], and refers to a report that indicates that medical evidence for medical devices may be lacking or may be insufficient. It does not detail problems associated with non-medical apps such as health, lifestyle and wellbeing apps. The Staff Working Document on Lifestyle and Wellbeing apps to which we referred above, does not elaborate on what safety issues could be relevant for these apps. The description provided by the Tender Specification and presented in the Consultation process thus offers the starting point for discussing the safety of health, lifestyle and wellbeing apps.

2.2. A (serious) incident

The second element to cover is what characteristics or constitutive elements of danger, risk or harm can be discerned that could lead to safety being compromised such that it becomes unacceptable. While harm refers to (physical, economic or otherwise) damage that has materialized, danger and risk refers to potential situations, i.e. situations that have a probability of arising. Danger refers to an identifiable threat that could materialize;

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[6] Commission Staff Working Document (2014). On the existing European legal framework applicable to lifestyle and wellbeing apps, SWD(2014)135 final, p. 3. For the reference on the Directive on liability for defective products, see footnote 6 on the Staff Working Document on emerging digital technologies.

[8] http://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en

[9] EC (2014). Green paper on mobile health. p. 12.

risk refers to the probability a specific harm is caused. The safety of a software application is thus determined by the probable chance that the use of this application leads to harm that should be considered to be unacceptable.

A situation that is different from foreseeable situations, associated with a normal functioning of the application is termed an **incident**. The Medical Device Regulation (MDR) defines incidents as malfunctioning or the deterioration of the performance of a device.[10] Malfunctioning of a device may have various origins: defects in the hardware, such as a break-down of connectivity, a short circuit in the electronic components, a loss of power; defects in the software, such as incorrect software or a faulty upgrade of a new software version; defects in the data used for the software, such as lack of qualitatively sound data, missing data, data which are not sufficiently accurate. Incidents may go unnoticed, while causing harm to a subject. For non-embedded software, the cause of an incident should relate to the software used or the software used in combination with the data used. The software could be wrongly implemented (for instance because of a failure during an update, or because the updated software contains flaws), could be manipulated, or could be hacked.[11] Presuming the algorithms used to calculate outputs on the basis of data collected by the device on which the software is downloaded function as should be expected, a wrong output could be due to a mismatch between the non-embedded software and the data it uses (syntactic errors or semantic errors). The data could be out of range for instance, have the wrong format, overload the algorithm or be manipulated. The application itself could be used in situations for which it is not foreseen (again: data will then be out of range for a proper functioning algorithm). The interaction between the downloaded software and the device on which it is downloaded may function improperly. The software may be improperly downloaded without signalling this, access to data on the device could be flawed. Finally, the representation of the findings could be impaired, for instance because results are out of range, the interface used for the representation does not work properly, or the interface itself is manipulated. All these issues could lead to an incident, in which the device does not behave as expected due to some problem in which the non-embedded software is involved.

The Medical Devices Regulation defines a **serious incident** as an incident with "serious consequences, such as the death of a person, the temporary or permanent serious deterioration of the person's state of health or a serious public health threat."[12] This definition of a serious incident thus refers to the state of health of a person. In a more general sense a serious incident refers to compromising the functioning of a system in a way that causes serious financial, physical, material, or other forms of damage.[13] The focus of our study is on health, lifestyle and wellbeing apps, putting safety in the realm of health, lifestyle and wellbeing. From that perspective it makes sense to join the approach adopted in the MDR and considering a (serious) incident to refer to situations that may cause unacceptable harm to individuals, or that confronts individuals with an unacceptable

[10] MDR Art 2 (64): "'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect".

[11] See e.g. Hanna et al. 2011. The paper investigates potential software risks in medical devices. Main risks are associated with defective cryptographic security approaches and non-robust credential systems.

[12] MDR Art 2(65): "'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat".

[13] See footnote 10

danger or risk. The MDR continues with the identification of a number of risk classes – class I, class IIa, class IIb and class III – in which the first relates to risks that hardly infringe upon the health condition of a subject and the last one relates to serious infringements up to death.[14]

In our study we will use the description of an incident as posed by the MDR. The issues to be investigated are whether situations which are different from foreseeable situations are reported when using health, lifestyle and wellbeing apps. Having the focus on non-embedded software as causing the incident we will investigate whether the incident is caused by non-properly functioning of non-embedded software, by interaction flaws between the non-embedded software and the device in which it is embedded and by non-properly interaction between the data and the non-embedded software. We will not focus on incidents in which output is misinterpreted or misjudged, since these cannot be attributed to the non-embedded software as such.[15]

It has to be recalled that the Radio Equipment Directive and the MDR can apply in parallel when medical devices make use of the radio spectrum. In such a case, the delegated empowerment on software of the RED can address risks arising from connectivity issues between the device on which an app is downloaded and a server for instance that offers the app for download or a database to which the output of the app is communicated.

The study will also identify whether reported incidents with health, lifestyle and wellbeing apps make use of a differentiation in risk classes as is presented in the MDR.

2.3. Non-embedded software

This study relates to the safety of non-embedded software. The consultation document on health apps defines non-embedded software as "software that is downloadable on a device".[16] The Tender Specifications follow a similar line of reasoning: "Non-embedded software is to be understood as software which, at the time of its placement on the market or its availability to consumers, is neither contained nor otherwise included in a tangible medium (e.g. apps for download)." During the inception phase it became clear that the topic under study should be understood as downloadable software that adds functionality to the device on which it is downloaded, and that may come from a different source than the provider of the device itself.[17] This implies that responsibilities between the provider of the device and the provider of the application concerning risks associated with the use of the app may be different. Within this study we will study apps that are delivered separately from the device on which they are downloaded. Essentially, most health, lifestyle and wellbeing apps will be downloaded through use of portals such as the Apple App store and the Google Play store. Updates of applications will be offered through these app stores as

[14] MDR Appendix VIII, Chapter III Classification Rules, p. 141 ff.

[15] An exception needs to be made when misinterpretations are caused by faulty interfaces, i.e. by interfaces that do not meet Human Computer Interaction requirements (for instance using wrong colours to code for dangerous situations).

[16] Synopsis report, p. 1; "Only apps and non-embedded software that are downloadable on a device such as a personal computer, tablet or smartphone or accessible on a remote location (cloud) were covered by this consultation.".

[17] In the current cloud-service based organization of software packages a downloadable operating system would meet the description of the Tender Specifications but clearly is of no interest for the study.

well. While at present App stores request some essential requirements to be fulfilled, these do not relate to the safety features we investigate in this study.

2.4. Safety of health, lifestyle and wellbeing apps

On the basis of this succinct analysis we will take the description of safety as provided in the Tender Specifications as basis: Safety is understood as freedom from unacceptable danger, risk or harm, including [but really not only] security-vulnerabilities. Applying this to non-embedded software the connection to be made is how this non-embedded software may jeopardize safety by posing unacceptable danger, risk or harm. The focus of the study being on health, lifestyle and wellbeing, we have restricted our study to investigating how safety could be jeopardized by the use of health, lifestyle and wellbeing apps in terms of implications for a person. This health situation may relate to physical health and to mental health. The question to be answered is thus whether incidents are known in which unacceptable harm is caused to the mental or physical health of a person (or persons) due to the use of specific health, lifestyle and wellbeing apps. Clarity on "foreseeable use" may contribute to restricting risks and dangers for subjects thus reducing (potential) harm.

2.5. Measures to offer safety guidelines

The 2014 Green Paper and Staff Working Document poses the problem that safety may be a concern and request a more in depth investigation and proposition. Having investigated incidents (chapter 4) we will also investigate what eight typical Member States are currently undertaking in order to tackle potential safety issues of health, lifestyle and wellbeing apps. Initiatives could come from public authorities that feel responsible for safety issues. They also could stem from private organisations in order to organise the market. And they could come from civilian organisations that try to streamline public concerns. The kind of activities undertaken are presented and we subsequently present a brief analysis of these activities. In this analysis we involve results of the workshop held.

Measures to deal with safety can be of various kinds. First, legislation initiated by Member States might address safety issues. Second, soft law measures, such as standards setting and codes of conducts might support safety practices. Certification measures could be an instrument as well, and might help assuring safety practices. Concerning standards we may differentiate between national standards that refer to European standards that have been published in the Official Journal of the European Communities and European standards that have not been published in this Journal.

Codes of good practice may be established by organisations working in the sector under consideration. Such a code could be formally agreed upon and could lead to established quality trust marks. Certification schemes may play a role as well. In our study, the availability of Codes of good practice and certification schemes will be inventoried for health, lifestyle and wellbeing apps. For devices falling under the medical devices legislation, a CE-mark is obligatory. This CE-mark is part of the essential requirements a product needs to fulfil. For devices that do not fall under the medical devices legislation it should be checked whether other applicable legislation (such as the Radio Equipment Directive, the Machinery Directive or the Toys Directive) could enforce the use of the CE-mark, and whether this is already done in practice.[18]

[18] The kinds of products and services that are entitled (and obliged) to provide a CE-mark are limitative indicated in the various directives posing safety requirements for specific groups of products (such as toys, electrical

Finally, the Commission might offer guidelines that refer to how the safety of a product is assessed. This study will check the availability of guidelines available in Member States or by private organisations in assuring the safety of health, lifestyle and wellbeing apps.

3. HEALTH, LIFESTYLE AND WELLBEING NON-EMBEDDED SOFTWARE APPLICATIONS

3.1. Scoping the field under study

The European Commission is interested in understanding what activities are undertaken within Member States in order to cope with risks associated with health, lifestyle and wellbeing apps. This interest is especially triggered through the emergence of a large market for these apps. A recent market study mentions an availability of 259.000 health apps and an expected growth towards 635.000 health apps in 2025, or some 200 novel apps per day.[19] Over 60% of these apps relate to health and fitness apps. Apps focusing on fitness (67.564), wellness (27.518), nutrition (23.002), and chronic disease management (13.483) are the most widely used apps. On the other hand, the number of successful apps is limited. There are fewer than 50 apps that exceed the 10 Million downloads. Over 85% of apps is downloaded less than 5.000 times.[20] Success factors for high download numbers are, according to this market study, "high patient ratings, frequent updates, connectivity to medical devices or sensors and extensive clinical evidence".[21]

A recent study on the public adoption of mHealth applications, published on March 15th, 2018 by the Italian *Associazione Difesa Orientamento Consumatori* (Association for the Protection and Direction of Consumers, henceforth ADOC)[22] presented the results of a survey, named *I consumatori e le app per la salute, un'inchiesta sulla salute digitale* (Consumers and health applications. An inquiry on digital health),[23] about current trends on health, lifestyle and wellbeing applications among the Italian public. The results show that these applications have gained a strong popularity in Italy: seven interviewees out of

equipment, machinery, medical devices, lifts and personal protective equipment). See https://europa.eu/youreurope/business/product/ce-mark/index_en.htm (accessed 25 March 2018).

[19] BIS research (2018). 'Global Mobile Medical Apps market: Focus on Category, Type, Application, Countries, Patients, Market Share, and Competitive Landscape – Analysis and Forecast'. https://bisreasearch.com/industry-report/global-mobile-medicsal-apps-market-2015.html (accessed March 6th, 2018). The term 'health' is used here to indicate both medical devices and non-medical health, lifestyle and wellbeing applications. In the BIS-study the term 'medical' is used as a kind of common denominator.

[20] BIS Research (2018).

[21] BIS Research (2018).

[22] ADOC is an association of volunteers specialized in aiding consumers in several areas including telecommunications, energy, transport, tourism, the Internet, banking and finance. For further information, see http://www.adocnazionale.it/aree-operative/diritti-cultura-societa/, last accessed March 27th, 2008.

[23] For further information, see http://www.adocnazionale.it/consumatori-app-inchiesta-salute-digitale/, last accessed March 27th, 2008.

ten state that they use at least one application related to health,[24] wellbeing[25] or fitness[26]. The latter, in particular, are used by almost 50% of the entire sample. Wellbeing applications are instead the most installed, even when they charge a fee, and the majority of interviewees pay the most for them, because they think that they are the most useful. Most interviewees use mHealth applications on their smartphones (~80%), while activity trackers, tablets, and smart watches proved definitely less popular. These applications are more widespread among younger people, and in particular fitness apps are common among people aged 18-25, wellbeing in the 26-45 age range (these two application categories enjoy wider popularity among the male public), while health-related ones are more appreciated by users between 45 and 60 years of age, especially women. More senior citizens do not use mHealth applications, stating that they are not interested in them, do not feel confident in disclosing their personal data and do not know how to operate them.[27]

Many of these apps will not fall under the formal definition as presented in the European Medical Devices Regulation (Regulation 2017/745/EU). Basically, medical devices are devices that fulfil intended medical purposes, such as diagnosis, prevention, prediction, treatment, alleviation, monitoring of a medical condition, including injury or disability. [28] Apps offering dietary suggestions, apps measuring vital signs for wellness purposes or apps offering fitness recommendations will not generally qualify as a medical device.[29] A relevant criterion mentioned in art 2(1) of the MDR is the intended use of the device. If the purpose is not to be intended to be a medical one, the MDR is not applicable to these devices. This is the situation, for instance, for general-purpose devices, such as devices that do nothing more than storing, archiving, compressing or transferring medical data.[30] Embellishment of data just for representational purposes is also not considered to be a medical task.[31]

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[24] These applications, for example, are designed to provide advice during pregnancy.

[25] These applications, for example, are designed to improve sleep quality, or to attain relaxation or attention.

[26] These applications, for example, are designed to monitor exercise or sports.

[27] For the complete results of the survey, see

http://www.adocnazionale.it/wp-content/uploads/2018/03/Inchiesta-Salute-Digitale.pdf, last accessed March 27th, 2018.

[28] Definition of medical device (MDR, art. 2(1)): "'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; — investigation, replacement or modification of the anatomy or of a physiological or pathological process or stat; — providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: — devices for the control or support of conception; — products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point."

[29] K. Rübsamen & S. Sakellariou (2015). 'Mobile Health Apps: Are they a regulated medical device?', White & Case, p. 2. Since the assessment whether a device qualifies as a medical device is done on a case by case basis, it will depend on the precise characteristics of the app whether it will be qualified as a medical device or not.

[30] Rübsamen & Sakellariou, p. 2.

[31] Rübsamen & Sakellariou, p. 2.

The manufacturer is responsible for providing information about the intended use such that users can easily check this.[32]

An Italian study has shown that the public at large is not completely confident in health apps. [33] The major concerns stem from privacy of health data, genuine consent to data management, and the perceived lack of control on the side of authorities, mostly public but also private.[34] Many of these concerns (such as the concern for privacy) fall outside the scope of this study. Other concerns, such as the role of public authorities, will be taken into account.

3.2. The demarcation of stand-alone software as medical device or not.

In order to help developers in deciding whether their device should fall under the MDR, the European Commission has developed a set of guidelines, specifically dedicated to delineating medical devices in relation to the use of software.[35] The guidelines do not deal with software that is an intrinsic part of a medical device. The guidelines are only meant for stand-alone software. Mobile applications are in scope of the guidelines. Stand-alone software is defined as "software that is not incorporated in a medical device at the time of its placing on the market or its making available."[36] The guidelines offer a decision tree that enables the delineation of stand-alone software as software that brings the device under the medical device regulation by answering a few straightforward questions:

1. Is the software performing an action on data different from storage, archival, communication or simple search?
2. If yes, is the action of benefit for individual patients?

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[32] Recital 43, MDR. Art 10(11) MDR.

[33] S. Pari, M. L. Rizzo, L'utilizzo di applicazioni di mHealth: rischi e responsabilità, in C. Faralli, R. Brighi and M. Martoni, Strumenti, diritti, regole e nuove relazioni di cura: il paziente europeo protagonista dell'eHealth, Turin 2015, 133.

[34] As indicated in the Tender Specifications, issues concerning data protection and privacy are out of scope for this study. Though out of scope it shows that people are afraid that, by scienter or negligence, their data related to health and fitness may not be kept secret. As a matter of fact, only a scarce majority of health, lifestyle and wellbeing applications come with a privacy policy and often they are neither complete nor clear. Regarding the management of data collected and processed, users can only choose whether to give their total consent or to deny it, being then however prevented from using the application altogether. Moreover, users perceive these apps as being designed without any supervision or control being exerted by healthcare bodies and authorities, doubting their safety and reliability. Finally, viruses, spyware and magnetic interferences are also deemed potential dangers against an effective uptake of mHealth solutions, for it is believed they could cause dangerous electromagnetic interactions with medical devices, such as pacemakers.

[35] MedDev 2.1/6, July 2016. 'Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices.' The Guidelines are not binding. They offer 'guidance' without offering legal certainty with respect to whether following the guidelines will safeguard developers from legal claims.

[36] MedDev 2016, p. 8. This 'definition' of stand-alone software resembles the definition for non-embedded software in which we presume that this is also not incorporated in a device at the time of its placing on the market or its making available.

3. If yes, is it for a purpose as defined in the medical device regulation?[37]
4. If no (to question 3), is it an accessory of a medical device according to definition of art 2(2) of the MDR?[38]

A 'No' to question 1, 2 and 4 puts the standalone software outside the scope of being a medical device (or being a relevant accessory to a medical device). If the answer to question 3 is 'No', it still needs to be determined whether the software is an accessory of a medical device (question 4). This decision tree offers guidelines to defining stand-alone software that is in use for health, lifestyle and wellbeing applications and that fall outside the scope of the MDR. When turning the decision tree the other way around, stand-alone software that is indeed performing an action on data such as storage, archival, communication or simple search falls outside the MDR. Secondly, when the actions of the software are different from storage etc. but are not for the benefit of an individual patient, the software does not fall under the MDR. Thirdly, when the software is for the benefit of an individual patient, it still might lack an intended purpose that puts it in the realm of a medical device. This intended function relates to the definition of a medical device (see footnote 28). Finally, when it did pass the previous qualifications and thus seems to qualify as not being a medical device, it still could be an accessory to a medical device. When also this can be excluded, it is for sure that the stand-alone software does not qualify as a medical device and thus falls outside the MDR. The guidelines continue in the Annex with a number of illustrations to show how to deal with the delineation of medical devices from non-medical devices.

Table 1 presents an overview of the examples provided in the MedDev 2.1/6 guidelines. These examples include stand-alone software for devices that support in vitro diagnostic medical devices (IVD). For these devices, a separate regulation has been adopted.[39] They are a subset of medical devices, and as such they are out of scope for this study.

Table 1: Delineation for stand-alone software as a Medical Device (MedDev 2.1/6)

Type of application	Function	Assessment
Hospital information systems	Administrative functions; do not qualify as MD.	
Decision support systems	Automatic decision making on the basis of input data.	When influencing the decision of treatment of

[37] Given that these guidelines are formulated before the MDR was in force, reference in the guidelines is made to the predecessor of the Regulation (Directive 93/42/CEE; art 1.2a). Adaptation to the MDR is however straightforward.

[38] Again, the original reference is to art 1.2b of Directive 93/42/CEE. An accessory according to the MDR is "an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)" (art 2(2) MDR).

[39] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Type of application	Function	Assessment
		individual patients they are qualified as MD Examples: Radio therapy; Chemo therapy drugs dosage
Information systems	Information systems serve as electronic patient records.	EPR do not qualify as MD when it simply replaces a paper file Specific modules added to an EPR might qualify as MD in their own right. Example: a medication module
	Picture Archiving and Communication Systems are a manifestation of information systems.	PACS do not qualify as MD; they do nothing more than storing pictures and communicating these pictures.
Communication systems	Communication systems connect devices to each other and serve transmission and storage capacity. They can be fixed and mobile.	Communication systems are usually general purpose and do not qualify as MD. Specific modules added to a communication system might qualify as MD in their own right. Examples: software generated alarms based on patient monitoring (see also table 2). Telecare systems (home monitoring) do not qualify as medical device.
Web systems for monitoring of data	Usually used for communication with a medical device (f.i. an implanted device) and used for sending collected data over the internet or a landline.	When the web system is part of a medical device it qualifies as medical device. Example: monitoring of active implant such as a pacemaker.
In vitro diagnostic (IVD) software	Laboratories information systems and Work Area Managers	These software packages do not qualify as a medical device. Additional modules

Type of application	Function	Assessment
		might qualify as MD on their own right.
	Expert systems	Software that is intended to capture and analyze results obtained for one patient by one or more IVD devices to provide information falling within the definition of an IVD medical device is considered as a medical device in itself. Example: expert system providing differential diagnosis.
	Interpretation of raw data	When the software is necessary to render raw data, and these data are acquired by in vitro examination of body samples, the software is to be considered as an accessory to the in vitro device when it is specifically intended to be used with this IVD.
	Home care monitoring, wired or mobile	Stand-alone software for archiving or transferring data from the home environment to the healthcare provider is not considered to be a MD (IVD).

A second document provides additional insight in how the European Commission deals with the distinction between stand-alone software being a medical device and not being a medical device. The 'Manual on Borderline and Classification in the Community – Regulatory Framework for Medical Devices vs 1.18' (2017)[40] runs a special chapter on 'Software and mobile applications' (Chapter 9). The chapter makes explicit references to the MedDev guidelines to support its findings in delineating specific mobile applications as medical devices and others as not resorting under the MDR. Table 2 presents the analysis

[40] This Manual is the result of a shared understanding between European national Competent Authorities and industry stakeholders of the Medical Device Regulation and the In Vitro Diagnostics medical devices Regulation. It has no legally binding force. See https://www.qarad.com/news/new-version-of-the-borderline-classification-manual-published (accessed May 24, 2018).

of the Manual with respect to a number of existing mobile applications of stand-alone software.

Table 2: Examples of stand-alone software in mobile applications as MD and as non-MD (Manual on borderline and classification in the community, 2017.

Type of application	Functionality	Assessment
A mobile application for processing ECG	More timely and accurate diagnosis and treatment for the patient	Falls under the MDR (class IIa MD)
A mobile application for communication between patient and care givers while giving birth	Note taking, adding pictures during giving birth	Not a MD; use restricted to storage and search
A mobile medical application for viewing the anatomy of the body	Viewing anatomical details, presenting terminology, positioning and medical imaging	Not a MD; not used for the direct benefit of an individual patient
Qualification of software for interpretation of a guideline	Consulting/reading a guideline for classification of Malignant Tumours: introduction of information re. size of primary tumour, involvement of regional lymphatic nodes and metastasis	Intended use: facilitating search and use of a guideline. Not a MD
Qualification and classification of software for delivery and management of cognitive remediation and rehabilitation programme	Application uses targeted stimulation of cognitive functions (reasoning, verbal, visual, spatial and auditory memory, processing speed).	Intended use: for treatment of neurotrauma, degenerative and neuropsychiatric conditions. Falls under the MDR (class I)
Classification of software for information management and patient monitoring	Route and store data from bedside medical devices in EPR; remote consultation of patient's status, including alarms.	Intended use: in intensive care wards. One function (triggering alarm) puts the software under the MDR.
Mobile application for managing moles	Taking pictures of moles of the skin and storing these for consultation	Not a MD: simply storage of data. Not a part of another device.
Mobile application for the assessment of moles	Taking pictures of moles, storing and comparing them on the basis of image processing algorithms.	Performs an action on data other than just storage or search, for the medical benefit of an individual

Type of application	Functionality	Assessment
		patient. This places the device under the MDR.

The Manual highlights the relevance of the intended use, the condition that an application should do more than just simple search and storage and the condition that an application should be for the benefit of an individual patient. The applications discussed all are embedded in a healthcare situation, in which professional caregivers are responsible for the healthcare process and treatment.

For the many tens of thousands apps that can be downloaded from an *Appstore*, the connection with a healthcare institution can be far away, using the app for lifestyle and wellbeing situations. The intended use of these apps may be such that they do not qualify as a medical device. If not intended to be sold to the market of healthcare professionals and institutes or to patients in order to fulfil medical functions, there is no obvious reason why an app developer should want his or her app be qualified as a medical device.

While this could lead to a rather strict demarcation between non-embedded software that serves medical purposes for the benefit of an individual patient and non-embedded software which does not, the examples presented also indicate there is a grey zone of non-embedded stand-alone software applications that serve medical and healthcare purposes but still do not qualify as a medical app and, the other way around, of applications that do not intend to qualify as medical device but that could be seen as such. With the continuing spread of medical knowledge on diagnosis and treatment from the institutional healthcare environment into the 'outer' world, the number of applications that do not intend to be used as medical device but strictly speaking still do, will grow.[41]

[41] An example is an app that is integrated with a knowledge system that routinely scrapes data of public discussion fora in order to track successful treatments or side-effects of medication and that is intended to provide an offer to an individual. While this example is fictitious, it is based upon a Dutch research endeavour that researches potential uses of such an app.

4. SAFETY INCIDENTS WITH NON-EMBEDDED SOFTWARE APPLICATIONS FOR HEALTH, LIFESTYLE AND WELLBEING

One objective of our study is to present an inventory of safety incidents with non-embedded software applications for health, lifestyle and wellbeing. The MDR enforces that manufacturers of medical devices develop and maintain a system for post-market surveillance, thereby enabling an option to undertake action in case of safety incidents. For health, lifestyle and wellbeing apps that do not fall under the MDR, such obligations for the producers of these apps are hard to derive from existing directives and regulations. As indicated under section 2.1, it is not clear yet whether specific European directives and regulations are applicable to the safety of health, lifestyle and wellbeing apps. At present, no specific obligations for State organised market surveillance activities thus are enforced from legislation for health, lifestyle and wellbeing apps that do not fall under the MDR.

This implies that no surveillance system can be consulted that might deliver examples of safety incidents with health, lifestyle and wellbeing apps. The Tender Specifications request to consult case law in order to check for incidents and to derive State interventions that may have been caused by the assessment of these cases. Also other ways of checking for safety incidents are encouraged.

As indicated in chapter 1, we searched for incidents by a combination of keywords using Google. The results of this search are presented in section 4.1 hereunder. Next we checked for case law in four countries: France, The Netherlands, Italy and Spain. To remain on the safe side we used "software" and "security" (and the translation of "security" in French, Dutch, Italian and Spanish: "securité", "veiligheid", "sicurezza" and "seguridad" respectively). The results of this search are presented in section 4.2. After the workshop we sent around a brief questionnaire in order to invoke additional information on incidents by the participants of the workshop that was held on April 19th, 2018 in Brussels. These findings are also presented in section 4.2. Section 4.3 presents some conclusions.

One final remark needs to be made before presenting the findings. We are aware of the problem of underreporting: some incidents that might be attributable to non-embedded software in health, lifestyle and wellbeing applications will not be identified as incidents. Though we are not able to present a systematic overview of reasons for underreporting we want to point at some examples that demonstrate how this might occur:

- Too loose connection between the safety incident and the non-embedded software:
    - for instance following a wrong wellbeing advice is not recognized to stem from using out of range data in the app; or
    - becoming sick after having followed a (flawed) advice on nutrition by a wellbeing app is not related by the user to the use of the app.
- An app is hacked but the owner does not realise this; data and/or algorithms are manipulated, but the safety consequences are minor or are not recognised to stem from the hacked device.
- A safety incident is recognised and is attributed to the app, but the owner of the app has no idea where and how to report the incident.
- A safety incident is recognised by a medical professional, but the medical professional does not know where to report the incident.
- No surveillance practices are in place by competent national authorities due that responsibilities for identifying and reporting on these incidents are yet unclear, so no

'warning' system is invoked that might help raising awareness and indicating opportunities to report incidents.

Though experts underscore that underreporting will occur, they are not able to indicate what the size of this underreporting will be and what role this underreporting plays.[42]

4.1. Searching the internet for safety incidents.

Our expectation was that apparent incidents with publicly available health, lifestyle and wellbeing apps should leave a trace on the Internet. Traditional media would report on these incidents, civil organisations or patient organisations would promote reports on these incidents. Of course, an incident with health, lifestyle and wellbeing apps would not necessarily reflect a safety incident in the manner as indicated in section 2.2. Follow on check of the items raised by searching the internet should demonstrate whether an incident would fall under the definition of an incident as used in this study. We used a typical combination of keywords: (lifestyle OR wellbeing OR health) AND (safety OR security) AND apps AND (incident OR failure). The results of this search are presented in *Table* 3.

Table 3: Output of Internet search through selection of keywords.

lifestyle	well-being	health	safety	secu-rity	apps	inci-dent	failure	#hits	relevant hits in first 5 pages
x			x		x	x		4.3M	0
	x		x		x	x		6.2M	0
		x	x		x	x		29.1M	0
x				x	x	x		4.8M	0
	x			x	x	x		6.4M	0
		x		x	x	x		27.9M	0
x			x		x		x	6.7M	0
	x		x		x		x	44.6M	0
		x	x		x		x	59M	0
x				x	x		x	7.3M	0
	x			x	x		x	13.4M	0
		x		x	x		x	12M	0[43]

The results as presented in Table 3 should be interpreted as follows:

1. We selected internet hits through using the combination of keywords as indicated. Usually, this led to a total number of hits of a number of millions. Since the selection allows for hits that only refer to one single keyword or any combination of two or more

[42] Statements made during the expert workshop.

[43] One hit might point at safety incidents but on clearer observations did not tackle the security incidents we are interested in. See https://www.theregister.co.uk/2016/01/13/health_apps_security_flaws_arxan/ (last accessed 25 May 2018).

keywords, the overwhelming part of hits will not sensibly relate to what we are looking for.

2. We checked the first fifty hits manually for appearances of hits that refer to safety incidents. This check was rather open. The very moment a hit seems to refer to an event that could relate to a safety incident we checked the hit.
3. This did not lead to any manifestation of an incident as we were checking for. Some 'nearby' hits were found, for instance:
    a. A reference to a probable failing of a fertility app. This referred to the use of the app and not to a safety incident because of the non-embedded software.[44]
    b. A reference to failure by the NHS to secure for cybersecurity incidents. This reference did not articulate specific incidents, but merely referred to the possibility that health apps could be hacked.[45]
    c. An article presenting an overview of security incidents in healthcare sector (including security incidents of medical devices).[46]

Many other hits refer to health failures or health incidents and the use of apps to prevent these, to monitor health by specific applications, or present a generic overview on potential dangers of health care applications.

4.1.1. One safety incident on melanoma detection

The keyword approach missed one apparent hit. One incident that can be attributed to health, lifestyle and wellbeing apps is the incident on apps detecting melanoma. A melanoma is a form of skin cancer that can be quite aggressive. Early detection is relevant. Apps are available that have in-built algorithms that identify the probability that a user may have skin cancer on the basis of the analysis of a photo. Other apps send the photo to a dermatologist. A 2013 study analysed the performance of three apps based on algorithms and one app based on expert consultation. The study found that even the best algorithmic app still missed 30% of skin cancers.[47]

4.2. Searching for case law on safety incidents with health, lifestyle and wellbeing apps

For four countries we checked whether case law was available that dealt with safety incidents of non-embedded software in health, lifestyle and wellbeing applications. We did

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[44] See https://www.wired.com/story/natural-cycles-contraceptive-apps/ (last accessed 25 May 2018).

[45] See footnote 43.

[46] See https://www.helpnetsecurity.com/2017/09/27/healthcare-security-incidents/ (last accessed 25 May 2018). Overall, this report does not deal with security incidents of health, lifestyle and wellbeing apps that do not fall under the MDR. The distinction is however not always clearly to be made.

[47] See https://www.consumer.org.nz/articles/skin-cancer-apps (last accessed 31 May 2018). The study referred to is a 2013 study, published in Journal of the American medical Association Dermatology. Though the study identifies the possibility of safety incidents, it did not identify real incidents, being based upon a structured experimental setting. It was argued that improvement in the algorithms used should improve the quality of the app.

so for France, Italy, The Netherlands and Spain. As indicated in the introduction we used rather generic keywords in order not to miss case law.

4.2.1. Case law in France on safety incidents with health, lifestyle and wellbeing apps

For France we used the Legifrance.fr to investigate safety incidents with health, lifestyle and wellbeing apps[48]. This site offers access to court cases in France.

For reasons of background checks and completeness, we also looked at the Centre National de Recherche Scientifique (http://www.cnrs.fr/) and to one of the main French publication portals for scientific research (https://www.cairn.info).

Keywors used were: santé numérique, applications des santé, (risques ou incidents de) logiciel de santé et de bien-être, santé mobile, (risques ou incidents de) données sur la santé, (risques ou incidents liés aux) applications de santé.

The search in Legifrance did not yield cases that link to incidents connected to non-embedded software/ health, lifestyle and wellbeing apps. Legifrance links to institutions we have identified[49] as relevant for this topic, specifically the ANSM and the INDS[50]. However, also Legifrance did not report incidents related to application software for health, lifestyle and wellbeing.

Thirdly, a scan on the CNRS for working papers on digital health/eHealth/mHealth and health, lifestyle and wellbeing applications resulted in one (1) report from 2015 on the trend of eHealth and its potential in or for France[51]. Also here, the key arguments evolve around the data generated by such apps rather than the software itself.

4.2.2. Case law in Italy on safety incidents with health, lifestyle and wellbeing apps

As far as post-2014 Italian case law is concerned, a research on "Il Foro Italiano" database, using "software" and "sicurezza" as keywords, provided 56 items.

Among them, 37 of these were rulings by the Corte di Cassazione (Italian Supreme Court), five by lower courts, nine by the Tribunali Amministrativi Regionali (lower administrative courts), three by the Corte dei Conti (Court of Audit) and two by the Arbitro Bancario Finanziario (Banking and Finance Arbitrator).

None among them seems related to health, lifestyle and wellbeing applications.

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[48] This is the official online portal for legal documentation in France, see https://publications.europa.eu/en/web/forum_official_gazettes/france-oj

[49] https://www.legifrance.gouv.fr/rechSarde.do?reprise=true&page=1&lettre=

[50] See f.i.

https://www.indsante.fr/wa_files/rapport%20dexpertise%20juridique%20sur%20l%20evaluation%20de%20linteret%20public.pdf on the role of open data generated by for instance health, lifestyle and wellbeing apps in the context of public healthcare.

[51] http://i3.cnrs.fr/workingpaper/etats-des-lieux-de-linnovation-en-sante-numerique-rapport-remis-a-la-fondation-pour-lavenir/

Further research on the Garante per la protezione dei dati personali (Privacy Authority, that does not belong to the judiciary system) showed a June 22nd, 2016, n° 273, provision/measure addressing a Hospital in Rome on grounds of privacy, data processing, consent and digital Personal Health Record. It is worth mentioning that the proceedings seem to make reference more to a "near miss" than to an actual "incident" or "accident".

4.2.3. Case law in the Netherlands on safety incidents with health, lifestyle and wellbeing apps

For the Netherlands we searched the database of Rechtspraak.nl that contains all judgements and verdicts of the Hoge Raad (Supreme Court), the Raad van State (High Court), the Centrale Raad van Beroep (Central Appeals Court), the Gerechtshoven (Courts of Justice), the Rechtbanken (Lower Courts or District courts) and some other judicial organisations within the Netherlands (within the overseas domains that still belong to the Netherlands). Most relevant in terms of hits are the Gerechtshoven and the Rechtbanken.

A total of 197 court cases popped up, with 129 cases over the years 2014-2016, 44 cases in 2017 and 24 in 2018 (June 2018). The Lower Courts dealt with 122 cases and the Courts of Justices with 43. Some court cases count at least twice (e.g. in District court and in Court of Justice), sometimes even three or four times. We did not correct for this double counting. Of these 197 court cases not one case dealt with health, lifestyle and wellbeing apps.

27 of them were software related:

- Sixteen of these were related to child porn and/or sexual abuse
- Three were related to Intellectual Property Rights
- The remaining eight had varying backgrounds but far off from safety problems and apps.

4.2.4. Case law in Spain on safety incidents with health, lifestyle and wellbeing apps

As far as recent Spanish case law is concerned, a research on "CENDOJ" provided by "Consejo General del Poder Judicial" (General Council of Judiciary) using "software" and "seguridad" provided 1507 items. The user is allowed to read only the first 200.

None among them seems directly related to non-embedded health, lifestyle and wellbeing application-related accidents and incidents.

The closest one is a November 27th, 2017, n° 543, ruling, by the Audiencia Provincial of Vigo. It is related to software (most likely embedded, but not thoroughly clear) and the litigation didn't arise because of accidents or incidents, but because of a contract breach among a software developer and a medical firm.

4.2.5. Identification of court cases by workshop participants

Having held the workshop, we considered approaching the workshop participants with a brief questionnaire a good idea to check for additional information on court cases dealing with safety incidents with non-embedded software in health, lifestyle and wellbeing apps. Through survey monkey we approached all 34 participants. Again, the question was posed in a rather broad manner in order not to a priori exclude potential hits. We received a response of nine persons (26%). Of these nine persons, only one responded positively to the question whether s/he was aware of any court cases dealing with the safety of health,

lifestyle and wellbeing apps.[52] The respondent was however not able to provide additional information on the court case and noted that the information came from mass media without further clarification.

4.3. Conclusion

No single case law incident referring to a safety incident with non-embedded software could be derived from a keyword check on the Internet, an analysis in four European countries and a brief survey of workshop participants. Also, a brief survey of the App Association, done under its members did not yield examples of incidents.[53] This cannot be interpreted as decisive evidence that such case law does not exist at all within the Member States of the EU. At most we might conclude that it seems unlikely that such events will pop up, also given the results of the internet search.

[52] The question posed was: "Are you aware of any court cases dealing with the safety of health, lifestyle and wellbeing apps?"

[53] This brief survey had a response of 30 organisations over seven countries (with France leading with 19 responses), but no incidents were identified by the respondents.

5. COUNTRY STUDIES

5.1. Austria

In Austria, policy making with respect to mHealth resorts to the Ministry of Health. Regulatory issues are dealt with by the Austrian Bundesamt für Sicherheit im Gesundheitswesen (Medicine and Medical Devices Agency). A register of approved medical devices is maintained by the Hauptverband der österreichischen Sozialversicherungsträger. The official website of the Austrian Medicine and Medical Devices Agency presents headlines of the MDR.[54] No mention is made of procedures or approaches related to health-related non-embedded software services that do not fall under the MDR.

5.2. France

In France, policy making with respect to mHealth resorts to the Ministry of Health and more specifically to the Direction Générale de la Santé and the Direction Générale de l'Offre de Soins (DG Health and DG Healthcare services). Regulatory issues fall under the responsibility of the French Agence nationale de sécurité du médicament et des produits de santé (National Agency for Medicines and Health Products Safety).

The ANSM has commissioned a study related to the safety of medical devices.[55] The study has been executed in 2014 and 2015 and reported in 2016. It offers an overview of technical standards relevant for the safety of medical devices. It refers to acknowledged standards by ISO and CENELEC in developing, testing and producing software packages (including stand-alone software). Though it is not explicitly stated in the report, the perspective is focused on medical devices (as these are articulated by the Medical Device Regulation). It does not rule out the applicability of its recommendations to health related non-embedded software that does not fall under the MDR. Given that application of the standards is not obligatory but might infer good practice, they might become part of practice of health-related non-embedded software that does not fall under the MDR. No certification schemes are however available yet to demonstrate adherence to these standards.

The Haute Autorité de Santé (National Authority of Health) is an independent public scientific authority "with an overall mission of contributing to the regulation of the healthcare system by improving health quality and efficiency."[56] The Authority has no formal competence in enforcing regulations or code of good practice. It has an advisory role to national health institutes and to professional organisations of health care practitioners. It offers guidelines for clinical practice and has a number of committees dealing with upcoming clinical issues. One such committee, the Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS - Medical Device and Health Technology Evaluation Committee) is dedicated to the evaluation of medical devices. The Committee uses the French implementation of the Medical Device Directive as starting point. The Committee has decisional power in deciding whether

[54] https://www.basg.gv.at/en/medical-devices/

[55] ANSM (2016). Study on the safety of Medical Devices, report by Selma Ingenierie.

[56] https://www.has-sante.fr/portail/jcms/c_415964/en/has-profile?portal=c_2567632

procurement of specific medical devices should be reimbursed within the French health care insurance system.

The HAS published a report in which it offers so-called 'good practice guidelines' for health apps and smart devices.[57] The guidelines cover a broad range of issues: informing users, health content, technical content, security and reliability, usability and use. It presents ways to assess apps and devices on the topics offered. The guide refers to ISO standards that enable certification by app developers (ISO/IEC 90003 Software engineering and IEC/FDIS 82304-1 Health software). Use of guidelines offered in the report could be used as reference when deliverables are produced for registering, labelling, scoring, peer reviewing, benchmarking or offering a testbed to apps and devices. The report also makes a reference to the need to monitor the implementation of the guidelines.

5.3. Germany

In Germany, no single authority or ministry is responsible for health care policy on a federal level (this being the responsibility of the Bundesländer). The Unit Medical Devices of the Bundesministerium für Gesundheit (the Federal Ministry of Health) is responsible for the regulation of medical devices.

The Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM (Federal Institute for Drugs and Medical Devices) has produced a paper that helps differentiating between apps/stand-alone software that should be considered medical devices and other software that does not.[58] The paper presents the conditions under which apps/stand-alone software should be considered to be a medical device and thus requires safety procedures as indicated in the Medical Device Directive.[59] It follows the approach presented in the MedDev 2.1/6 Guidelines for stand-alone software and offers the same examples to indicate delineation between medical devices that fall under the directive and medical devices that do not.

In 2016, the Federal Ministry of Health commissioned a study by the Peter L. Reichert Institute for Medical Informatics and the Hannover Medical School. The study was named CHAnces and RISks of MHealth Applications (CHARISMHA). The full report (German only) comprises 370 pages. The management summary - also available in English - still comprises some 40 pages.[60] The full study documents a large variety of perspectives on health apps and clearly does not stick to the delineation issue. The study is one of the first in its kind that offers an encompassing perspective on issues that the various stakeholders in this market should take into account. Separate chapters deal in depth with issues related to the use of mHealth apps for prevention, for diagnosis and therapy and for research purposes. Risks of mHealth are studied as well as the various challenges associated with the introduction of mHealth apps. The final chapters offer perspectives to layman users, to

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[57] HAS (2016). Good Practice Guidelines on Health Apps and Smart Devices (*mobile Health* or *mHealth*) – Assessment and improvement of practice. https://www.has-sante.fr.

[58] BfARM (2015). Orientierungshilfe 'Medical Apps'. See https://www.bfarm.de/SiteGlobals/Forms/Suche/Servicefunktionsuche_Formular.html?resourceId=3496612&input_=3494902&pageLocale=de&templateQueryString=Orientierungshilfe+medical+apps&submit.x=10&submit.y=8 for a full overview on papers/reports and presentations on this topic.

[59] This information is still valid now the MDR has been adopted.

[60] Chances and Risks of Mobile Health Apps (CHARISMHA) – Abridged Version, Albrecht, U.-V. (Editor), Hannover Medical School, 2016. urn:nbn:de:gbv:084-16051809293. http://www.digibib.tu-bs.de/?docid=00060023

professional users and to developers and producers of how to cope with the various challenges offered by mHealth apps.

The regulatory framework that is put forward relate – next to the Medical Device Act[61], being the German implementation of the EU Medical Device Directive – to the German eHealth Act.[62] The eHealth Act deals especially with eHealth patient records and with the needed infrastructure to promote use and exchange of digital patient data. In that sense it is less directly relevant for the issue of health-related apps that do not fall under the MDR.

The chapter of the CHARISMHA study dealing with the risks of mHealth apps discusses a variety of risk factors. It looks at risks because of failure in the functionality of the app and failure in the use of the app. It pays attention to failure in diagnostics and failure in therapy. It also mentions safety risks related to abundant use of an app (called "Whatsappitis"). It discusses technical issues such as the potential impact of electromagnetic radiation on the body. Impacts upon wellbeing, be it corporeal or mental, and impacts upon potential denial of personality rights (for instance the right to act as an autonomous person) are considered as well. Finally, the risks of data analytics for personal rights and the potential intrusion by third parties are discussed.

The three final chapters of the study are dedicated to what layman users, professional users and app developers/manufacturers could contribute to a more sensible and aware integration of Health apps in the healthcare system. Reference is made to the obligations following from the German Medical Device Act and to the opportunities offered by certification seals and marks.

A third report that can be mentioned is the report produced by the IGES institute in combination with the AiM institute.[63] This report mainly documents essential requirements to cope with the Medical Device Act, and is especially focused on medical devices.

5.4. Italy

In Italy[64] issues related to mHealth and in general health, lifestyle and wellbeing applications are dealt with by the Ministero della Salute (Ministry of Health), in particular by the Direzione generale dispositivi medici e servizio farmaceutico (DG Drugs Supply and

[61] In German the Gesetz über Medizinprodukte, adopted 7 August 2002, and transposed to the German version of the Medical Device Regulation in 2017.

[62] See "Gesetz für sichere digitale Kommunikation und Anwendung im Gesundheitswesen"; German Health Ministry, Federal Register 12-21-2015: http://www.bgbl.de/xaver/bgbl/text.xav?SID=&tf=xaver.component.Text_0&tocf=&qmf=&hlf=xaver.component.Hitlist_0&bk=bgbl&start=%2F%2F*%5B%40node_id%3D'946289'%5D&skin=pdf&tlevel=-2&nohist=1.

[63] K. Neumann et all. (2016). 'Digital healthcare products: Leveraging opportunities – developing safe routes to the market'. Study report for Techniker Krankenkasse. Berlin.

[64] The main statute in this area, under Italian law, is D. lgs. n° 46, of February 24th, 1997, *Attuazione della direttiva 93/42/CEE concernente i dispositivi medici* (Implementation of the aforementioned Medical Devices Directive, henceforth DLGS46/97).

Medical Devices)[65] that is part of the Dipartimento dell'innovazione (Department of Innovation).

From a legal perspective, uncertainty rests upon the apportionment of liability among the different parties involved, including the producer of the mobile phone on which the applications are installed, the internet service provider, the software developer and the practitioner who recommended its use. The legal framework for generic wellbeing applications that do not amount to medical devices, being simply health related, is also not sufficiently defined:[66] in that case, only general product liability[67] seems applicable.[68] Some directions to users, practitioners and application developers on the theme of mHealth are provided in a few documents, released by governmental, para-governmental and non-governmental Italian bodies.

In 2014, the Associazione Italiana Sistemi Informativi in Sanità (Italian Association for Information Systems in Healthcare)[69] published a paper on *Mobile Health: innovazione sostenibile per una sanità 2.0* (Sustainable Innovation for a 2.0 Healthcare).[70] The report provides a multidisciplinary analysis of mHealth, with a focus on Italian experience and case studies; after a description of the European framework, the authors focus on processes, technologies, infrastructures and software that have been implemented both in hospitals and outside, with a thorough analysis of contemporary telemedicine. Further developments deal with the empowerment of patients, customer workflow management and issues related to privacy and information security. On the whole, the authors recommend a "VAST-Health" approach (Value Assessment Tool for ICT Healthcare project) that suggests a multidimensional assessment. It is recommended to first undertake a

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[65] This authority is responsible for providing detailed regulation and for consulting, authorising, surveillance, research and cooperation in the area of drugs and medical devices. For further information, see http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153, last accessed March 26th, 2018.

[66] S. Stefanelli, *Le problematiche connesse alla qualificazione giuridica delle App medicali*, in C. Faralli, R. Brighi and M. Martoni, *Strumenti, diritti, regole e nuove relazioni di cura: il paziente europeo protagonista dell'eHealth*, Turin 2015, 143.

[67] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, O.J.L. 210, 07/08/1985 (henceforth PLD) is now implemented by the Italian Consumer Code (D. lgs. n° 206, of September 6th, 2005, henceforth ICC) artt. 114 and ff..

[68] It is open to discussion whether a software should be considered a product for the purposes of the PLD. Literature has suggested stressing the differences between a standardized software and a custom-made one, whereby only the former would meet the requirements and thence be subject to such regulation. For some discussion, see G. Di Rosa, *Linee di tendenza e prospettive in tema di responsabilità del prestatore di servizi*, in *Europa e diritto privato*, 1999, I, 719; F. Fedrizzi, *I prodotti difettosi*, in P. Cendon (ed.), *I danni risarcibili nella responsabilità civile. I singoli danni*, VII, Turin 2005, 287; M. Hazan, *Attuata la direttiva 99/44/CE. Si rafforza la tutela del consumatore*, in *Contratti*, 2002, 397; A. Maggipinto, *Note in tema di responsabilità civile e software difettoso*, in *Rivista di Diritto, Economia e Gestione delle Nuove Tecnologie*, 2005, 5, 1, 764; P. G. Monateri, *La responsabilità civile*, in R. Sacco (ed.), *Trattato di diritto civile*, Turin, 2006, 709; G. Ponzanelli, *Responsabilità per danno da computer: alcune considerazioni comparative*, in *Responsabilità civile e previdenza*, 1991, 653; A. Zaccaria, *La responsabilità del «produttore» di software*, in *Contratto e impresa*, 1993, 303.

[69] This association was founded in 2003 and is focused on giving visibility to ICT-in-healthcare through several working groups of its own and through participations to research teams, panels and similar projects. For further information, see www.aisis.it., last accessed on March 23rd, 2018.

[70] http://www.aisis.it/it/attachment/2ae99027-05bd-4584-ba47-6006b4079474/Mobile-20Health.pdf, last accessed March 23rd, 2018.

context definition, then to assess ICT projects through qualitative elements, then to evaluate quantitative aspects, and finally to assess risks and needs.

Moreover, the Italian region Emilia Romagna, through its Commissione Regionale Dispositivi Medici (Regional Committee about Medical Devices)[71] developed a report in 2012/2013, entitled *M-Health e linee di indirizzo sull'utilizzo delle applicazioni medicali per dispositivi* "mobile" (mHealth and guidelines on the use of medical apps for mobile devices),[72] identifying new risks emerging from the use of these applications, including data protection, potential virus infections of the hospital networks, and induced recklessness on the side of doctors and nurses. The latter is in particular due to dual nature of electronic devices, usable for both work-related tasks and entertainment purposes. The document then provides a classification table to distinguish between applications that are qualified as medical devices and those that are not, pursuant to the aforementioned MEDDEV, as well as a series of specific examples.[73] Furthermore, regional operating recommendations for physicians and hospital staff – divided among general rules,[74] before-commissioning rules[75] and after-commissioning[76] rules – are put forth, suggesting how to implement mHealth solutions in the environment of the Hospital.

The Comitato Nazionale per la Bioetica, henceforth CNB (National Bioethics Committee,[77] that belongs to the Italian Prime Minister's Office), delivered a "Mobile-health" *e applicazioni per la salute: aspetti bioetici* report in 2015 ("Mobile-health" and health-apps: bioethical issues).[78] The report exposed that the safety and effectiveness of applications is often not assessed by qualified medical personnel, and IT companies might abusively qualify their applications as non-medical, so as to ease the designing and manufacturing processes, avoiding stricter standards.

The CNB also found that an abuse of health, lifestyle and wellbeing applications may on the one hand lead to addiction, that is both a morbid attention to one's fitness at an individual level, and a social competition that would ultimately lead to further medicalization. On the other hand, it might induce patients to avoid recurring to a

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[71] This committee is responsible for the surveillance on medical devices and for doing research on costs and benefits of products and technologies. For further information, see http://salute.regione.emilia-romagna.it/farmaci/dispositivi-medici, last accessed on March 23rd, 2018.

[72] http://salute.regione.emilia-romagna.it/documentazione/leggi/regionali/linee-guida/m-health_linee_applicazioni_medicali_2013.pdf, last accessed March 23rd, 2018.

[73] Among the former, the report showed a diabetes manager, while among the latter it mentioned a sphygmomanometer.

[74] For example, medical applications should not be used when time is crucial, because access inconveniences are always possible.

[75] For example, it is useful to classify applications according to FDA guidelines for a better risk assessment.

[76] For example, ascertaining that actual use is consistent with original statements and that instructions are known and followed.

[77] The CNB, founded in 1990, is an institute that provides both consulting to the Government and to the Parliament, and information to the public at large on bioethics issues. It delivers opinions, that are regularly published on the institutional website (https://bioetica.governo.it, last accessed on March 23rd, 2018) and cooperates with similar committees at an European and International level. It is composed of professors and researchers in various fields, according to the principles of interdisciplinarity and pluralism.

[78] http://bioetica.governo.it/media/170734/p121_2015_mobile-health_it.pdf, last accessed March 23rd, 2018.

specialized practitioner, interpreting medical data independently and eventually choosing one's own therapy. The CNB, therefore, formulates a series of guidelines, targeting different subjects and stakeholders, including policy-makers, businesspeople, technicians and academics at large. These include establishing uniform international criteria for distinguishing medical devices, limiting the amount of data that apps are allowed to gather, and creating an observatory to constantly assess the applications themselves.[79] Enterprises are encouraged to develop useful and reliable applications, while pursuing a more effective pre-contractual communication with potential users.[80] Overall, the CNB suggests the need for a multidisciplinary approach, encompassing IT technicians, designers, physicians and social scientists, and additional research on the topic, especially on personal and relational identity, addiction and technological vulnerability.[81]

Finally, the Italian Istituto di Vigilanza sulle Assicurazioni Private,[82] an insurance surveillance body released a document on current trends in the insurance sector, entitled *Le nuove polizze sulla salute*: *la* digital health insurance (New healthcare insurance policies: digital health insurance).[83] Insurance companies are starting to provide insured parties with wearables and other devices that can process and save data about physical fitness and overall health; data is then used to recalibrate insurance premiums or provide insured persons with other forms of advantage. While promoting a healthy lifestyle, digital health insurance may trigger privacy issues if companies match health and non-health related data, unknowingly left on the Internet,[84] in order to emarginate less attractive parties. In this manner the mutuality principle may be threatened. This principle implies the sharing of losses among a defined group of individuals exposed to the same risk.

5.5. The Netherlands

In the Netherlands, the Ministerie van Volksgezondheid, Welzijn en Sport (Ministry of Public Health, Well-being and Sports) is the responsible ministry for policy making. The agency, responsible for the regulation of medical devices, is the Inspectie Gezondheidszorg en Jeugd - IGJ (Inspectorate for Health care and Youth). The Rijksinstituut voor Volksgezondheid en Milieuhygiëne – RIVM (National Institute for Public Health and the Environment) has a unit working on medical devices. The Dutch Raad voor de Volksgezondheid en Samenleving – RVS (Council for Public Health and Society) is an advisory body to the government and produces requested and open advises. In 2015, it reported on legal issues concerning eHealth.

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[79] Recommendations n° 1, 4 and 5.

[80] Recommendations n° 3 and 6.

[81] Recommendations n° 2 and 8.

[82] IVASS is an independent administrative authority, ensuring stability of the insurance system and protection to consumers. Among other functions, it oversees technical and financial aspects of insurance companies, makes sure that applicable statutes are respected, cooperates with other Italian authorities and deals with complaints. It exists since 2012 and its head is the Director General of the Bank of Italy, in order to strengthen cooperation between bank and insurance surveillance. For further information, see www.ivass.it, last accessed March 23rd, 2018.

[83] https://www.ivass.it/consumatori/azioni-tutela/indagini-tematiche/documenti/digital_health_insurance.pdf, last accessed March 23rd, 2018.

[84] For example, useful information could be inferred from Google search patterns or social network posts.

The IGJ keeps track of official safety warnings with health care applications.[85] The public portal that has been created to this end contains slightly more than 500 warnings. The keyword 'medical technology' ('medische technologie') produces one hit. The hit is related to the functioning of a catheter and is thus not related to health apps. Up till now, no safety warnings are reported that deal with mHealth applications. The IGJ has a role in observing and surveying the application of new technologies in the health domain. Its inspectors check manufacturers producing medical equipment and medical devices. Class I manufacturers are checked as well. Risk assessment helps in deciding which organisations should be closely monitored. The IGJ does not deal with non-embedded software applications for health, lifestyle and wellbeing that do not fall under the MDR. Up till now, the IGJ has not received any indication that these applications might pose risks that make them susceptible to heightened attention by the Inspectorate. No incidents have been reported nor have incidents come to the attention of the inspectors. The IGJ is not involved in any activity relating to this aspect. Up till now the IGJ considers this not to be an issue that should be followed actively.[86]

The RIVM is investigating health apps that fall under the MDR. It intends to produce an overview that helps differentiating between apps that fall under the MDR and apps that don't. In practice deciding whether an app is a medical device is not always straightforward matter. Up till now not many (if any at all) incidents were found with apps (be they medical device or not). Even when a CE-mark is lacking for an app that should be considered a medical device this does not mean that the app poses a risk to its users. The lack of reported incidents may be a sign of an apparent absence of incidents.[87]

The RVS produced an advisory report in 2015 on legal aspects of eHealth.[88] The study observes that liability issues in health care usually will be related to conformity issues with the Wet op de Geneeskundige Behandelovereenkomst (WGBO – Medical Treatment Agreement Act). The WGBO regulates consent and information concerning the treatment of patients in a care situation. It binds professional caregivers and patients. Failure of medical devices in use in healthcare situations will *prima facie* be attributed to the medical professionals and not to the manufacturer of the device.[89] In a situation that the healthcare institute is not liable, responsibility will be handed over to the manufacturer.[90] The study continues with investigating the need for a separate regime for liability when this concerns eHealth applications. Dutch government has indicated in a response to the Green paper of the European Commission on mobile health[91] that it does not yet see a need to seek novel legal remedies for liability issues in this domain. The report indicates that the IGJ (then IGZ) has indicated it will start monitoring the certification of medical apps. It will use the

[85] See https://www.igj.nl/onderwerpen/waarschuwingen-medische-hulpmiddelen/documenten

[86] Interview IGJ, March 1, 2018.

[87] Interview RIVM, March 20, 2018

[88] M. de Lint (2015). 'Juridische drempels voor toepassing (consumenten) eHealth' ('Legal barriers for the application of (consumers) eHealth'). Achtergrondstudie. Den Haag: RVZ

[89] De Lint, p. 26.

[90] De Lint, p. 26.

[91] EC (2014). 'Green paper om mobile health', COM(2014) 219 final.

Medical Devices Directive for this purpose.[92] The report indicates that this monitoring will not be sufficient to guarantee safety of medical apps. It refers to the problem that, for many eHealth apps, certification can be done by the manufacturers themselves (when Class I risks) and that manufacturers may decide not to do so. The report indicates directions that may help to counter the identified problems. It sticks close to the formal agreement between care professional and client (based on the WGBO) and suggests a lighter variant for eHealth applications.[93]

The advisory report has been integrated in a more encompassing report produced by the RVS on eHealth.[94] The report deals in depth with the emergence of eHealth applications that may be beneficial for clients and that are manufactured by novel parties. The report concludes that awareness is needed for the potential mixture of formal care with personalized advice that clients may obtain by using self-measurement tools of different kinds. The report does not refer to incidents that might trigger additional alarms in the use of apps that give personalized advice or enable self-measurements. No such incidents are reported. In the longer term, the report observes, self-monitoring and measuring equipment may either increase the need for medical help or decrease this need. The potential increase is related to novel doubts that may arise when vital signs are frequently measured. The decrease could be a consequence of the provision of personalised advice through the applications used.

A number of institutes in the Netherlands offer help in deciding whether a software service such as an app should be considered a medical device or not. The Koninklijke Nederlandse Maatschappij voor de bevordering van de Geneeskunst (KNMG – Royal Dutch Medical Association) has published a guide that offers practical assistance in deciding whether an app meets specific quality requirements.[95] The checker can be used for apps that should be considered medical devices, falling under the Medical devices legislation, and for apps that are aimed at monitoring, tracking, storage and other supportive facilities (including communication) that do not fall under the Medical Devices legislation. The quality issues raised concern on functionality, ease of use, content quality, (clinical) relevance, data protection and security issues.

The Dutch Gemeenschappelijke Geneeskundige Diensten (GGD – Community Health Services) has developed an Appstore in which it offers guidance with respect to the quality of health related apps.[96] The website enables users to find appropriate apps in a number of segments such as 'body', 'psyche', 'wellbeing', 'happiness', 'relations' and 'daily life'. Apps within these segments are assessed by experts in the field on a number of dimensions: usability, reliability, privacy and security, relevance (effectiveness). The site contains over 200 apps and is intended to keep on growing over the years. Cooperation with knowledge institutes and professionals enable to check quality requirements.

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[92] Medical device directive, in Dutch translated in the Wet Medische Hulpmiddelen (adapted since 1-1-2018). http://wetten.overheid.nl/BWBR0002697/2018-01-01.

[93] De Lint, p. 35.

[94] RVZ (2015).' Consumenten eHealth' ('Consumers eHealth') Den Haag: RVZ.

[95] KNMG (2016). Medical App Checker – Evaluation of Mobile Medical Apps. https://www.knmg.nl/actualiteit-opinie/nieuws/nieuwsbericht/medical-app-checker-a-guide-to-assessing-mobile-medical-apps.htm

[96] https://www.ggdappstore.nl/Appstore/Testmethode

Finally, an initiative in the academic world aims to organize a large community to promote quality assurance of health apps.[97] The initiative intends to gather 20.000 students that help in reviewing the quality of the by now over 350.000 health apps that are available worldwide.[98]

5.6. Spain

In Spain, issues related to health, lifestyle and wellbeing applications are dealt with by the Ministerio de Sanidad, Servicios Sociales e Igualdad (Ministry of Healthcare, Social Services and Equality), in particular by the Dirección General de Salud Pública, Calidad e Innovación (Directorate General of Public Healthcare, Quality and Innovation) that is part of the Secretaría General de Sanidad y Consumo (Secretariat General on Healthcare and Consumption).[99]

The main body of regulation in this field is offered by the *Real Decreto* 1591/2009, of October 16th, *por el que se regulan los productos sanitarios* (Royal Decree regulating Health Devices, henceforth RD1591/2009) enacting the MDD.[100]

A good practice was introduced by the Agencia de Calidad Sanitaria[101] in the Autonomous Community of Andalusia (henceforth Agp) consisting of thirty-one policy recommendations,[102] dealing with a wide variety of aspects, ranging from design,[103] quality of information[104] and service provision[105] to privacy.[106] In particular, the Agp requires developers to both be transparent, when stating the owner of the company, and to clearly identify potential risks their applications might give rise to. With a similar purpose of ensuring the highest grade of consumer protection, it is demanded of them to provide technical support with a fixed response time, to inquiry about any relevant technical issue, and the possibility to disable all advertisements presented by the application during its

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[97] https://www.leidschdagblad.nl/leiden-en-regio/nationaal-centrum-ehealth-leiden

[98] https://nos.nl/nieuwsuur/artikel/2219489-van-de-350-000-gezondheidsapps-is-maar-een-deel-betrouwbaar.html

[99] This organ provides hygienic and sanitary requirements for human consumption products, promotes health, prevents illnesses and, among other tasks, coordinates surveillance in the healthcare field. For further information, see http://www.msc.es/organizacion/ministerio/organizacion/sgralsanidad/dgsaludpublicaF.htm, last accessed March 26th, 2018.

[100] This Royal Decree implemented the aforementioned Medical Devices Directive, 93/42/EEC.

[101] It is a public agency, it is part of the Consejeria de Salud (Health Council) of the Junta de Andalucia (Government of Andalusia). It aims at reaching a higher quality in the delivery of healthcare services, it is involved in certification duties, education and dissemination. For further information, see http://www.juntadeandalucia.es/agenciadecalidadsanitaria/, last accessed March 23rd, 2018.

[102] http://www.juntadeandalucia.es/agenciadecalidadsanitaria/estrategia-de-calidad-y-seguridad-en-aplicaciones-moviles-de-salud/, last accessed March 23rd, 2018.

[103] Recommendations 1 to 4.

[104] Recommendations 5 to 15.

[105] Recommendations 16 to 20.

[106] Recommendations 21 to 31.

functioning. When an application complies with the abovementioned recommendations, it receives a special seal, called *Distintivo AppSaludable*, that certifies its quality and reliability, and allows its listing on the site of the Andalusian agency, then achieving a relevant and clear signalling effect for all potential users, that might subsequently entrust that specific solution rather than one deprived of the same labelling.

Other institutions, such as Observatorio Zeltia,[107] IDIS (Institute for Development and Integration in Healthcare)[108] and Cátedra ISC[109] of the Universidad Rey Juan Carlos, pursue a similar informative objective, and published a report in 2014 on the 50 best health related applications available in Spain.[110] To do so they underwent the assessment of them based on four criteria: (i) content, (ii) design, (iii) awards, and (iv) utility. With respect to content, the authors privileged high quality, rigorous applications, backed by scientific papers and trials that guarantee the functioning of the apps. Design and user experience criteria attained instead the assessment of their interactivity and attractiveness to the users, while utility addressed the way in which the needs of the patients were tackled. Awards and prizes earned by the applications were then also taken into consideration. All such efforts of distinguishing reliable and trustworthy applications are well understood in light of the overall favour that Spaniards seem to express with respect to mHealth devices.

Pursuant to a 2014 report[111] on opportunities and challenges arising from mHealth – taking into account the various perspectives of the different players involved, including providers, patients and payers – the public at large displays high expectations, and consumers are eager to enjoy mHealth services. To the contrary, however, the health industry does not appear as prepared in fully exploiting the economic potential of such a propensity. The report assessed mHealth readiness in ten countries, according to four pillars, ranging from (i) openness to mHealth, to (ii) regulatory, reimbursement and business model, (iii) technology and (iv) impact. Spain performed for the most among the average of all developed countries, yet it was the second best as far as perception of regulatory environment, reimbursement and business models were concerned. This implies that lack of proven business models and the regulatory framework are not perceived as key barriers.

Moreover, 53% of the population believed mHealth devices would be widely accepted in the near future, while only 12% disagreed and 35% were unsure. When asked what

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[107] Observatorio Zeltia is a study group aimed at fostering innovation processes in the pharmaceutical and healthcare areas, through publications, dissemination and conferences. For further information, see http://scyr.es/portfolio-item/observatorio-zeltia/, last accessed March 23rd, 2018. Zeltia is a Spanish pharmaceutical and chemical group, established in 1939.

[108] IDIS is a foundation (http://www.fundacionidis.com, last accessed March 24th, 2018) established in 2010 and focused on private healthcare. It is made up of representatives from hospitals, clinics and insurance companies and is focused, among others aims, on reshaping relationships between public and private healthcare in Spain.

[109] Cátedra ISC (Innovation, Health and Communication Chair) is a joint initiative of Observatorio Zeltia and the Universidad Rey Juan Carlos in Madrid, aimed at supporting research and dissemination in the healthcare sector.

[110] http://www.theappdate.es/static/media/uploads/2014/03/Informe-TAD-50-Mejores-Apps-de-Salud.pdf, last accessed March 24th, 2018.

[111] PriceWaterhouseCoopers report is titled Emerging mHealth: Paths for growth, http://pwc.com/gx/en/healthcare/mhealth/assets/pwc-emerging-mhealth-full.pdf, last accessed March 24th, 2018. For detailed data about Spain, slides are provided https://www.pwc.com/gx/en/healthcare/mhealth/assets/pwc-emerging-mhealth-chart-pack.pdf, last accessed March 24th, 2018.

motivated their conclusion, most interviewees chosen among the general public mentioned – with higher rates than the average interviewees coming from other countries, assessed in the same report – "convenient access to healthcare provider", "access to better quality healthcare" and "greater control over health", as the primary advantages of such solutions that would make them desirable.[112]

To the contrary, the "cost", as well as the "lack of relevant applications" were identified as the major drawbacks towards the diffusion of mHealth solutions. The "lack of knowledge about services" is instead feared substantially less than among corresponding individuals coming from other developed countries. Spanish physicians instead, in greater percentages than professionals of other nationalities, mentioned "improved quality of care", "easier access to care" and "better internal processes", as the major advantages brought about by similar applications. Yet, they feared that the "culture of medical professionals", and the "lack of information on mHealth" as well as "privacy and security issues" would prevent a wider acceptance. Among all, the latter is, however, deemed much less serious an issue by Spanish professionals rather than by foreign practitioners.

Next to Andalusia also Catalonia is strongly involved with mHealth. It implemented a Catalan Master Plan on mHealth,[113] which comprises the creation of a website, named AppSalut,[114] that presents several health and social care applications, available for free download and operating on both iOS and Android devices. The site provides healthcare applications developed for most kinds of illnesses and ages, as well as for a general fit and sporty lifestyle, while social care applications are developed for specific group of individuals, such as people with addictions or disabilities. Each application has been evaluated according to 120 criteria that belong to four categories, namely (i) usability, (ii) technical issues, (iii) clinical issues and (iv) security.[115] Criteria are also classified as alternatively compulsory, recommendable or desirable. Failure to comply with compulsory criteria leads to the exclusion from the website, while compliance with recommendable and desirable ones leads to a better numeric grade. For example, it is compulsory for all applications to provide information on cookie policies, while it is recommendable that applications provide a form of utility or advantage to users, and it is desirable that they provide a way for the user to contact the owner of the application. Every application, moreover, is graded pursuant to a "stars-scale" system, by physicians and patients that have used it and decided to express their opinion about its functionality and usability.

Every application is also classified according to two criteria, technological and content-related. The former is a function of the amount of sensitive data processed and the impact, intended as the potential number of users interacting with it, and ranges between one and three (three the highest). The latter asses the kind and quantity of medical advice provided

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[112] See slides 43 and 44.

[113] This plan was approved in 2015, in order to strengthen the link between health and social welfare services and the general public, through smartphones, tablets and laptops, to furthermore induce a general improvement of healthcare. The mHealth.cat office was created by Fundació TicSalut (an agency within the Ministry of Health, that promotes ICT in the field of healthcare) in collaboration with the Mobile World Capital Barcelona Foundation (an initiative focused on innovation, transformation, and empowerment). For further information, see http://www.ticsalut.cat/observatori/mhealth/en_index/, last accessed March 27th, 2018.

[114] https://appsalut.gencat.cat, last accessed March 27th, 2018.

[115] For further information and the complete list of criteria, see https://appsalut.gencat.cat/documents/22056/0/Guía+criterios+proceso+acreditación.pdf, last accessed March 27th, 2018.

to the user and its impact, as already defined, and varies according to the same scale. Assessment is intended as a service for owners and developers of medical applications, and is thence provided at a price that varies according to the technological level, number of services offered, and screens displayed.[116] Practitioners can recommend applications that are featured on AppSalut and, provided that patients have given their consent, can have access to patients' data, stored on their medical record via a Digital Health Platform.

5.7. Sweden

In Sweden, policy making in the field of health is a shared responsibility of the government, the regions and the counties. The Swedish Läkemedelsverket (Medical Product Agency) is the responsible agency with respect to the regulation of medical devices. The Consumer Agency supervises compliance with the Swedish Product Liability Act (SFS 1992:18).[117] Consumers can claim compensation under the Product Liability Act for injuries caused by safety deficiencies. They must demonstrate the injury to be caused by a safety deficiency of the device they used (Product Liability Act). They also can bring a claim under Swedish Tort Law (SFS 1972: 207). For the Tort law causality between the injury and safety deficiency does not have to demonstrated. A causality demonstrated between the use of the product and the injury is sufficient. The Group Claim Act (SFS 2002: 599) enables groups of claimants to act together in a class action. So far, no group claims have been dealt with in relation to deficiency of medical products.[118]

Concerning the regulation of medical devices, the MPA was already active in 2009 in starting a project group to produce guidelines for medical devices as these were introduced in the amended Medical devices directive of 2007. The group became part of a larger European group that led to the development of the MedDev 2-1/6 guidelines for stand-alone software.[119] On the basis of the results of the MedDev working group the MPA continued its work. Though the value of the MedDev guidelines are obvious, the focus of these guidelines is very much on offering guidance to producers of software, and less for users, laymen and professionals. The MPA produced a guideline in 2013 that was meant for notified bodies, manufacturers and manufacturers organisations, health care institutions, authorities and other parties.[120] The guide provides guidance on the interpretation of the Medical Devices Directive and presents additional information on risk management systems, clinical evaluation of medical information systems, installation and maintenance of medical information systems in networks and procurement and issues referring to CE marking. It ends with providing a number of examples that demonstrate how the guidelines work out in these situations (running from electronic patient record systems to picture archiving and communication systems and applications for cell phones and tablets). Many of the examples are similar to the ones provided in the Manual that was

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[116] For further information on levels and prices, see https://appsalut.gencat.cat/documents/22056/0/Clasificación+por+niveles+y+coste+económico.pdf/16deb53c-b515-4833-892a-5c0aa06f4f1b, last accessed March 27th, 2018.

[117] H. Waxberg et al. (2017). Medicinal product regulation and product liability in Sweden: Overview.

[118] Waxberg (2017). p. 14.

[119] The updated version of the MedDev guidelines for standalone software was released in 2016.

[120] MPA (2016). 'Medical information systems – guidance for qualification and classification of standalone software with a medical purpose.' https://lakemedelsverket.se/english/product/Medical-devices/

provided by the Commission. Again, the focus is on how to identify a medical device, rather than identifying non-medical devices.

Regulatory reforms are foreseen for the implementation of the MDR in Sweden. These reforms deal with shifting the responsibility of notified bodies with respect to medical devices from the Swedish Board of Accreditation and Conformity Assessment to an authority to be appointed by government.[121]

The Swedish Standards Institute is involved in the work of the European Committee for Standardisation, CEN, aiming at developing standards for health applications that do not fall under the MDR. CEN approved a proposal for setting up a working group that should focus on the necessary standards. The working group will adopt the BSI PAS277 as starting position.[122]

5.8. United Kingdom

The National Health Services (NHS) bear responsibility for developing a policy and a vision on health care service provisioning in the UK. The Medicines and Healthcare products Regulatory Agency (MHRA) is the agency that regulates medical devices. Related to the regulation of medical devices, the British Standards Institute (BSI) has published in 2015 a so-called Publicly Available Specification on health and wellness apps.[123] This PAS 277 is a so-called Code of practice. It contains non-binding guidelines that are, at least partly, based upon accepted standards and that are intended to promote best practices in dealing with the subject. PAS 277 is based upon a lifecycle approach of health and wellness in which quality criteria for data management and guidelines for software development practices are promoted for health, lifestyle and wellbeing apps. PAS 277 builds upon a number of British standards (of which several have an EU equivalent or are just the national implementation of international and European ISO/IEC standards). It is based upon BS EN 62304 (software development life cycle). It uses BS ISO/IEC 25010 and BS ISO/IEC 25012 that define quality criteria, covering a broad range of topics such as:

- Regulatory and legal compliance
- Functionality
- Usability and user experience
- Reliability, performance and scalability
- Security and privacy
- Safety
- Compatibility and portability
- Maintainability

It builds upon an app project life cycle, that runs through planning, requirements analysis and research, design, application testing, implementation, release, maintenance and finally discontinuation of app project life cycle.

Risk management makes use of ISB0129 (which offers an approach towards clinical risk management) and BS EN ISO 14971 and is directed at covering situations in which the app is used differently from intended, a situation of incomplete or ambiguous requirements

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[121] Waxberg (2017). p. 15

[122] Interview Jenny Acaralp, SSI, March 12, 2018.

[123] BSI (2015).' PAS 277: 2015 Health and wellness apps – Quality criteria across the lifecycle – Code of practice.

need to be taken into account, and a situation of mistakes/oversights during implementation.

November 19, 2014, the British Royal Academy of Engineering and the Academy of Medical Sciences organized a joint meeting on 'Health apps; regulation and quality control'.[124] Some 30 participants from academia, industry and government discussed the situation arising around health apps. The meeting yielded a number of key issues:

1. Complexity of regulation: Developers would benefit from support by the legislator in offering a roadmap through a regulatory landscape that many find confusing.
2. Suitability of current regulatory framework: the existing framework still uses physical devices as focal point; 'virtual' products such as apps pose different risks. Harm can be caused by improper apps and by improper use of apps. The challenge is to find the appropriate middle ground between too harsh regulation that might hamper innovation and regulation that is not fit for the job.
3. Vigilance and monitoring: given the newly arising landscape, the lack of pro - activeness at the side of MHRA raises concern.
4. Obstacles to app use: the lack of clarity on liability issues might hamper the uptake of health apps.
5. Generating and evaluating the evidence of clinical utility: the standard clinical trials are not fit for testing the utility of health and wellness apps. More centres specializing on evaluating apps are needed.
6. The role of aggregation services: app libraries could play a role in quality assurance.
7. Software development practices: common practices of rapid app development are not suitable for current regulatory practices and standards.

While not all conclusions deal directly with the safety of apps, the overall perspective demonstrates awareness for facets of safety that may be of relevance for non-embedded software applications in health, lifestyle and wellbeing not covered by the MDR.

Recently, the NHS announced that it will enforce the use of the SCCi0129 standard for all sales done to NHS. [125] Up till then, products with CE-mark were released of this obligation, but it becomes now obligatory for self-certified CE-marks (Class I other than measuring/sterility). NHS maintains a website in beta version with healthcare apps that meet specific quality criteria. Only one of the approximately 40 apps bears the seal 'NHS approved' which means that clinical evidence for the functionality of the app is available. Three apps bear the seal 'Being tested in the NHS', which means that these apps are in a programme of gathering clinical evidence. All apps meet specific quality criteria, but the website does not provide information on the kind of criteria used.

[124] Academy of Medical Sciences and Royal Academy of Engineering (2015). Health apps: regulation and quality control – Summary of a joint meeting held on 19 November 2014 by the Academy of Medical Sciences and the Royal Academy of Engineering.

[125] Information received from Dr. Charles Lowe, Managing Director Digital Health & Care Alliance (DHACA), February 2, 2018.

Next to NHS three private organisations are active in assessing the quality of apps. Two of these organisations use publicly available information from the Internet for the assessment; the third organisation also interrogates developers.[126]

[126] The three organisations are Iqvia (https://www.iqvia.com), Orcha (https://www.orcha.co.uk/) and Ourmobilehealth (https://www.ourmobilehealth.com/). Information received from Dr Charles Lowe, February 2, 2018.

6. OVERVIEW RESEARCH FINDINGS ON SAFETY INCIDENTS AND MEMBER STATE ACTIVITIES

In this chapter we will analyse the findings of the previous chapters in the light of the twofold challenge of this study:

1. The presentation of an overview of incidents and court cases on incidents dealing with safety of non-embedded software in health, lifestyle and wellbeing apps.
2. The presentation of an overview of Member State activities on the safety of non-embedded software in health, lifestyle and wellbeing apps

We will first present the main results of the search for safety incidents and relate this to incidents that were considered to have a health impact upon users (section 6.1). As will become clear these incidents do not fall under the category of health incidents the study was focusing upon. Second, we will with outline the commonalities among the country studies in terms of actors involved, initiatives taken and state of the art (section 6.2). Third, some final thoughts on the implications of our findings are presented (section 6.3).

6.1. No identification of safety incidents

The investigation of court cases on the safety of health, lifestyle and wellbeing apps did not result in the identification of relevant cases. This being the case for four countries studied, we still cannot conclude that court cases on the safety of health, lifestyle and wellbeing apps are not available in EU Member States. In combination with the absence of hits through internet search by means of a number of keywords, we may conclude however that the probability that other Member States will have court cases that deal with the safety of health, lifestyle and wellbeing apps is not very high.

Incidents that were reported and that might be considered to pose a safety threat to persons were related to issues caused by or inferred by the use of the app but not by issues caused by the software of the app.

One such incident which was reported and which received quite some coverage in the press was the use of an app that enabled women to measure their fertility.[127] The app scans the body temperature in order to advice when women will be in their fertility period and when not. While the presented figures still make it hard to decide about the level of protection the app provides, according to the statistics presented the app scores at least as good as any other contraceptive and meets its promises. The Swedish Södersjukhuset Hospital in Stockholm, that was able to trace the 37 women using this app out of a group of 600 women that came to the hospital for an abortion, stated that it felt the need to report this incident to the Swedish MPA, notwithstanding the fact that the app may meet the guidelines it produced itself concerning the failure rate of the outcomes of the measurements.

In this situation, the incident that was reported has no direct connection to the safety of the app, and no direct connection to the non-embedded software on the app. The fertility app is considered to be a medical device, given that the Södersjukhuset hospital will notify the MPA on this incident. The MPA only deals with problems associated with devices that are covered by medical device legislation. So, this incident does not count as an incident

[127] https://www.engadget.com/2018/01/15/natural-cycles-app-unwanted-pregnancies/ (accessed 29 March 2018).

of non-embedded software related to health, lifestyle and wellbeing that is relevant for this study.

Other problematic situations were reported but not supported by specific incidents. One such situation concerns the information provided by so-called pro-ana websites that may enforce eating habits that may have detrimental health consequences for persons following these habits. A Dutch journalist supports a mother in reporting these websites at the Dutch police.[128] The accusation of the mother is that these websites have led to sincere health problems of her daughter (who had to be hospitalized as a consequence of following the advice of one of these websites) and she accuses the makers of these websites of being responsible for these health problems.

One of these websites is apparently created by a young woman who offers tips and tricks and who spreads the message that only being thin can create happiness.[129] The website does not offer any 'medical' advice but may be influential on other (young) persons. This website however, though it could have adverse health consequences through the messages it spreads, does not pose a safety or security problem that is relevant for this study.

The absence of reported incidents on the internet, in reports and in court cases cannot be taken as decisive evidence for the absence of these incidents. As stated before, arguments can be provided that this is a situation of underreporting rather than strict absence.[130]

6.2. Overview of European Member States' activities to guarantee safety of non-embedded software in health, lifestyle and wellbeing

The country studies enable drawing some initial conclusions on the activities undertaken by Member States in order to guarantee safety of non-embedded software for health, lifestyle and wellbeing. We received information from seven Member States. Information from Austria is lacking. No response has been received upon our request, and unfortunately we have not been able to distil documents uncovering the Austrian approach through Internet searches. This is no indication for an absence of Austrian activity in covering the safety of non-embedded software related to health, lifestyle and wellbeing. Within time and resource constraints we have not been able to explore the Austrian situation in depth.

Looking at the remaining seven Member States, some generic observations can be made. By and large, these observations are similar in all Member States studied.

First, the distinction between an application resorting under the Medical Devices legislation and an application not resorting under the Medical Devices legislation is a very relevant demarcation criterion for competent national authorities that are responsible for the surveillance of the safety of medical devices. The existence of a grey zone, comprising of applications of which it is hard to tell and difficult to assess whether it should be considered a medical device, is acknowledged. The guidelines that shed light on this demarcation, are used to decide which devices should be considered medical devices and which not. When it shows that an application does not fall under the Medical Devices legislation at present

[128] https://www.rtlnieuws.nl/rtlboulevard/marielle-doet-aangifte-tegen-pro-ana-sites ("Marielle reports pro-ana-sites at the police"). (accessed 28 March 2018).

[129] See: https://myproanasite.webnode.be/braken (accessed 28 March 2018)

[130] See page 22. For one, safety incidents may go unnoticed. For another, individuals notifying a safety incident do not know where to report such an incidents. For a third, responsibilities for investigating safety incidents by public authorities are unclear.

no competent national authority bears responsibility for investigating and assessing safety issues with these applications.

Table 4: Distinct features when dealing with medical devices and non-medical devices

	Medical Devices legislation applies.	Medical Devices legislation does not apply.
Risk classification	Through CE-mark; class I self-assessment; class IIa, IIb and III through notified bodies	No risk classification available
Market surveillance	Manufacturer is obliged to establish a post-market surveillance system	No surveillance mechanism is enforced.
Responsible agencies	Usually inspectorates of health care	No agencies bear responsibility for investigating and assessing safety issues.

Table 4 indicates that in case of non-embedded software for health, lifestyle and wellbeing that do not fall under the Medical Devices legislation, monitoring requirements concerning the safety of this software are absent. And as a consequence, no public authority at present bears responsibility for surveying or monitoring safety incidents related to non-embedded software of health, lifestyle and wellbeing apps. In the Member States that were studied in this study, several authorities responsible for surveying the safety of medical devices pay attention to health, lifestyle and wellbeing apps that do not fall under the Medical Devices regulation. This will be treated in more depth in the next section. This is however not a formal responsibility of these agencies.

6.3. Shifting the focus: from frontend to backend safety

The safety of consumers can be infringed in a number of ways:

- a proper functioning application can have adverse effects, because this is intended to be so (example: the pro-ana websites);
- it can have adverse effects because it is used under conditions not foreseen ('foreseeable use; the 'fertility app' might serve as an example');
- it can lead to wrong uses because of problems in understanding the output of the app;
- its functioning may be jeopardized because of technical problems (faulty measurements, for instance because of failing sensors);
- it may malfunction because of deliberate infringements (adverse intrusion of the device, for instance by hackers).

Finally, unforeseen and illegitimate data use may jeopardize the privacy of users. We do not take these infringements into account because these are covered by data protection legislation (the General Data Protection Regulation).

The first infringement mentioned is not relevant for this study. The application functions as intended. No safety incident (in terms of deviation from foreseeable use) is present. No safety incident with the non-embedded software is present.[131]

The second is not relevant either. The topic of this study is the infringement of safety of non-embedded software, notwithstanding the intended use of the application on which the software is downloaded.[132]

The third infringement deals with the interface between the app and the user. Such an interface could be part of non-embedded software on the device. Even when the software functions properly, the output may lead to safety problems for the user when the user is not able to correctly interpret the output.

The distinction between the fourth and the fifth infringement is an internal problem with the non-embedded software that accidentally occurred vis-à-vis deliberate attempts by an external attacker to disturb a proper functioning of the software. Internal problems may have various origins: wrong download of an update, use of data that are not compatible with the algorithm used (out of range, wrong format), a bit that flips.

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[131] See the argumentation presented in section 6.1.

[132] See the argumentation presented in section 6.1

Our study did not identify concrete examples of safety incidents that can be traced back to either situation three, four or five. While one can find references to safety problems of health IT and medical devices, this has not led to the identification of real safety incidents with health, lifestyle and wellbeing apps not covered by the medical devices legislation.[133] Given the apparent concern for these safety incidents, our study identified several initiatives by public and private organisations within Member States that offer support for how to produce safe health, lifestyle and wellbeing applications. In the following section these initiatives will be summarized and will be inventoried using the above presented distinction in combination with the distinction presented in terms of instruments that might be applicable (see section 2.5).

6.4. Actions in European Member States in promoting safety of non-embedded software for health, lifestyle and wellbeing

Notwithstanding the absence of clear incidents that necessitate actions by supervisory authorities, the country studies showed all countries to undertake precautionary measures. These measures focus on providing guidelines for app developers. In Table 5 we have summarized the activities per country.

Table 5: Overview of practical guidelines for the identification of medical devices and non-medical devices, including recommendations for dealing with non-medical devices.

Country	Organisation	Activity	Year
Austria	--	--	--
France	ANSM	Study with recommendations on design and applications of medical devices	2016
	HAS	Good practice guidelines on health apps and smart devices	2016
Germany	BfArM	Guidance on differentiating between medical devices and non-medical devices	2015
Italy	CRDM	mHealth and guidelines on the use of medical apps for mobile devices	2012
The Netherlands	KNMG	Mobile Medical App Checker	2016
	RIVM	Guidelines medical devices	2017
Spain	ACS	Website with guidelines on design, use and assessment of health apps	2012 onwards
	AppSalut	Guidelines for the accreditation process, accompanying the AppSalut website	

[133] During the workshop, several examples were provided. Identifying patient safety problems associated with information technology in general practice: an analysis of incident reports - http://qualitysafety.bmj.com/content/25/11/870; An analysis of electronic health record-related patient safety concerns - https://www.ncbi.nlm.nih.gov/pubmed/24951796

Sweden	MPA	Medical stand-alone software guidance	2013
UK	BSI	PAS277 – Health and wellness apps guidelines	2015
	MHRA	Medical software guide eHealth apps	2017

All countries provide guidelines to help differentiating between medical devices and non-medical devices. The organisations providing these guidelines are medical professional organisations. A number of countries also provide guidelines for non-medical devices, i.e. health, lifestyle and wellbeing applications that do not fall under the Medical Device legislation (France – HAS, Netherlands – KNMG, Spain – ACS and AppSalut, and UK – BSI). All guidelines are based upon or refer to the documentation provided at EU level.[134] All organisations except for the UK BSI organisations are medical professional organisations.

The BSI PAS guidelines are the starting document of an activity planned to be undertaken by the CEN. France, Germany, Italy, The Netherlands, Sweden and the UK have supported an initiative to create a separate working group within the CEN TC251 that will deal with the development of guidelines for non-medical devices. The working group is expected to start its activities in due time. A stakeholder inventory has been made which has yielded support by a number of involved organisations (especially app developers, app providers and branch organisations of app developers).[135]

An inquiry within this study done by branch organisation ACT showed that app developers are very interested in being provided with clear guidelines. They fear the lack of harmonised guidelines over Europe which endangers the development of innovative applications for the consumer market. Uncertainty on quality standards might hamper innovation.[136] The survey set out by ACT delivered 32 responses of organisations over seven European countries. The respondents noted differences in the implementation of the GDPR over Member States (due to the discretionary competences on health issues in the various Member States) that might hamper or delay innovations. They also reported that few incidents are known, but some are known to have occurred with activity trackers and some with connected objects. These incidents were not exposed.

Finally, and relevant for this study, is the observation that professional organisations are active in this domain, providing guidelines and helping members but that only few are active in both software and health practices.

In *Table 6* the actions undertaken by the Member States are grouped to the kind of activity they purport. The table differentiates between various types of soft measures:

- Standards
- Guidelines
- Certification

[134] The MedDev 2-1/6 guidelines and the Manual on borderline and classification of medical devices – version 1.18.

[135] Interview Sirin Golyardi, NEN, 29 March 2018

[136] Interview Brian Scarpelli and Alexander Prenter, ACT, 16 March 2018. Survey performed among ACT members, March 2018.

- Assessment of apps in use

Standards offer the most formal (though not necessarily legally enforceable) way to organise a specific way of working and meeting quality criteria. They are the result of self-regulation by market parties. Guidelines can be based on standards, but can also rely on quality criteria developed for a specific purpose. Certification can be based upon legal criteria. Certification bodies need to meet specific quality criteria including audit and control. Assessing apps that are available is a kind of service offered by public health authorities in an attempt to help the general public in selecting reliable and effective health, lifestyle and wellbeing applications.

Table 6: Country specific activities grouped according to the kind of measure propose

Country	Organisation	Measure	Feature
France	HAS	Good practice guidelines	health content, technical content, security, usability
Italy	AISIS	Health assessment	context definition, quantitative and qualitative assessment, privacy and information security
Italy	CNB	Guidelines	data limitation, app observatory
Netherlands	KNMG	Guidelines	functionality, usability, content quality, relevance data protection and security
Netherlands	GGD	Appstore plus assessment	usability, reliability, privacy and security, effectiveness
Netherlands	RUL	Public assessment	quality of information, reliability, effectiveness, privacy and security,
Spain	Agp - Andalucía health	Good practice - guidelines	design, quality of information, service provision, privacy
Spain	Agp - Andalucía health	Certification	quality and reliability
Spain	Cátedra ISC	Guidelines	content, design, awards, utility
Spain	Catalunia health	Appsalut website	usability, technical issues, clinical issues, security
UK	BSI	PAS277	regulatory and legal compliance, functionality, usability, reliability, privacy and security, safety, compatibility, maintainability.
UK	NHS	Appstore plus assessment	quality, clinical evidence, security, usability

6.5. Conclusions

This study started with searching for safety incidents with health, lifestyle and wellbeing apps. Key concepts used in this study were the kind of applications searching for (health, lifestyle and wellbeing apps), the relevant components of these applications and the kind of incidents looking for (safety incidents, i.e. incidents with an impact upon the safety of the users).

Various approaches were used in order to track safety incidents. Because of the expected media awareness for safety incidents, the study started by searching for hits through internet search. No single safety incident that matched the composed criteria was however found when checking with a set of keywords.

Secondly, the study checked for four countries (France, Italy, The Netherlands and Spain) for case law related to software incidents. To keep the chance for finding a hit as big as possible just two keywords were used in the domestic language in domestic databases containing case law: 'software' and 'security' (except for France that used a larger variety of keywords). In none of the consulted databases we were able to locate a case dedicated to the safety of health, lifestyle and wellbeing apps.

A brief survey to participants of the workshop on the safety of health, lifestyle and wellbeing apps was sent in order to check whether they were aware of case law on safety incidents with health, lifestyle and wellbeing apps. None of the nine responses identified an incident that met our criteria.

The contributions of the speakers at the workshop confirmed the lack for visible and reported incidents. They did offer interesting information regarding the problem of how to reconcile the problem of medical devices with the role of software in a medical device[137], the presence of a quality system to identify errors and failures in case of failing health IT and its role in assuring quality of medical products[138], and the need to develop a more encompassing standardisation system in order to cope with health, lifestyle and wellbeing applications that function at the borderline with medical devices[139].

The overall conclusion on the basis of this fact finding is that at present no safety incidents concerning non-embedded software of health, lifestyle and wellbeing apps that do not fall under the Medical Devices legislation can be found in public sources. The only reference found was to a situation that may arise but that did not lead to identifiable incidents.[140]

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[137] See the contribution of Carole Rouaud (CPME) in which she among others mentioned Case C-329-16 SNITEM vs French State, a court case that identified the potentiality of software in a medical device being a medical device by itself. See http://curia.europa.eu/juris/document/document.jsf?text=&docid=197527&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=467223 (last accessed May 30, 2018).

[138] See the contribution of Stuart Harrison (NHS) in which he identified a large number of sources in which the safety of medical and health IT software was investigated and in which risk management systems to cope with these safety issues have been developed and implemented.

[139] See the contribution of Tobias Schreiegg (COCIR) in which he identified the relevance of standard IEC 82304 that helps bridging the gap between Software as a Medical Device and General Health Software.

[140] The app identifying potential melanoma's clearly poses safety threats. We were however not able to point at specific incidents caused by a misrepresentation of the app of a skin mole.

The study checked for relevant legislation applicable to safety incidents of health, lifestyle and wellbeing apps. This does not lead to a conclusive view. At present the General Product Safety Directive and the Product Liability Directive are studied on whether and to what extent they might be applicable to health, lifestyle and wellbeing apps. The Radio Equipment Directive can be invoked.

In the second stage of this task, the team focused on eight European Member States: Austria, France, Germany, Italy, the Netherlands, Spain, Sweden and the United Kingdom. Of each country it was investigated whether specific activities were undertaken in order to deal with potential safety issues of non-embedded software in health, lifestyle and wellbeing apps. Activities could run from legal initiatives to soft law in the form of guidelines, promoting good practices and standard setting.

The investigation showed that many countries undertake activities to help citizens in assessing the relevance, adequacy and effectiveness of health, lifestyle and wellbeing apps. No general framework to do so is yet in place, though many guidelines that are produced focus on a similar set of activities: medical content, security and privacy, usability, effectiveness. Medical content relates to the reliability of the information provided, without the requirement of clinical evidence (though some guidelines refer to clinical evidence as potential basis). Effectiveness is also hard to evaluate, given the lack of formal and enforceable guidelines in practice. For many countries, medical professional organisations and medical quality assurance organisations have the lead in these initiatives. Next to this, the CEN has decided to start a working group under TC251 that will address the safety of health, lifestyle and wellbeing apps. This initiative uses an earlier initiative of the UK BSI that resulted in PAS277.

The overall conclusion is that, notwithstanding the lack of reported incidents at this point in time, many countries are fully aware of the need to offer some kind of transparency with regard to the safety of health, lifestyle and wellbeing apps to the public at large. Especially medical professional organisations and public organisations active in assuring quality of health care develop a set of activities to help controlling the safety of health, lifestyle and wellbeing apps. CEN has created a working group that in due time will come with a proposal for standardization of health, lifestyle and wellbeing apps, based upon the BSI PAS277 guidelines. This proposal will also help in preventing potential safety incidents of health, lifestyle and wellbeing apps, while assuring the quality of these apps given the purposes they serve.

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8. INTERVIEWS

Name	Profile/Company	Date
Johan Krijgsman	Inspectie Gezondheidszorg en Jeugd, NL	1 March 2018
Jenny Acaralp	Swedish Standardisation Institute	16 March 2018
Brian Scalpelli and Alexander Prenter	ACT – The App Association	16 March 2018
Arjan van Drongelen	RIVM, NL	20 March 2018
Henrik Moberg	Ministry of Health, SW	23 March 2018
Jacco van Duivenboden	Nictiz, NL	26 March 2018
Sirin Golyardi	CEN/NEN	29 March 2018

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