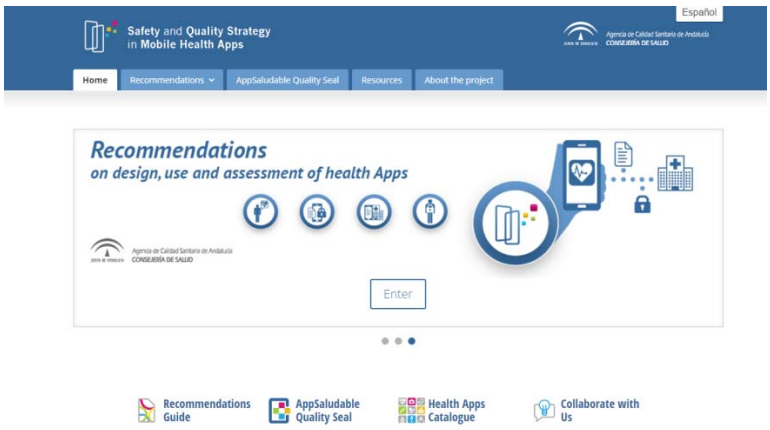
Andalusian mHealth Strategy – Use case

1. Regulation – Quality and safety in Health apps

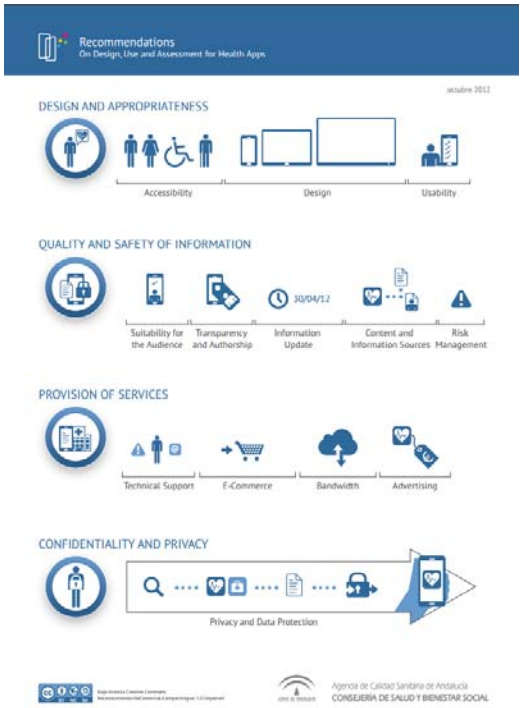
1.1 Recommendations for the Design, Use and Evaluation of Health Apps

In 2012, the Andalusian public health system defined their own “Recommendations for the design, use and evaluation of health apps”.



All the information is publicly available at http://www.calidadappsalud.com/en

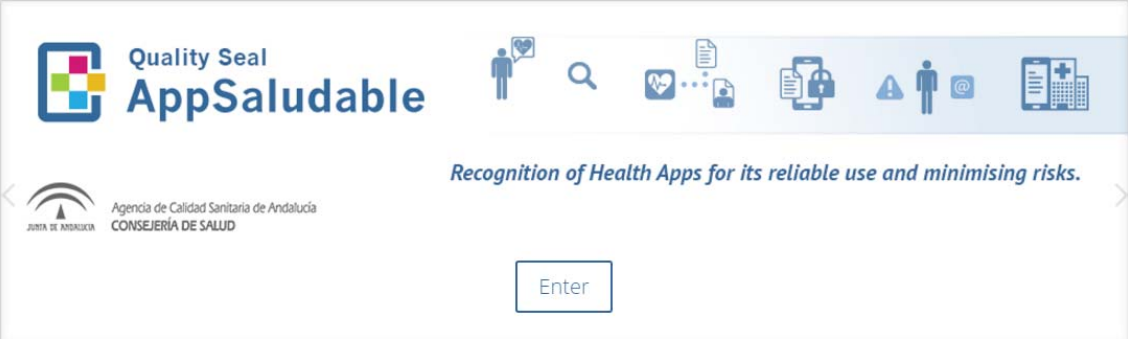
The recommendations are divided into four blocks as shown in the figure below:



The full set of recommendations (31) and the subsequent requirements is fully detailed in Annex 1.

1.2 Appsaludable Distinctive

This body of recommendations the assessment guidelines supporting the Appsaludable Distinctive, launched in 2013, as the first quality seal for health apps in Spanish worldwide.



It is based on a self-assessment + external assessment methodology, as it is further explained in the following URL http://www.calidadappsalud.com/en/distintivo-appsaludable/

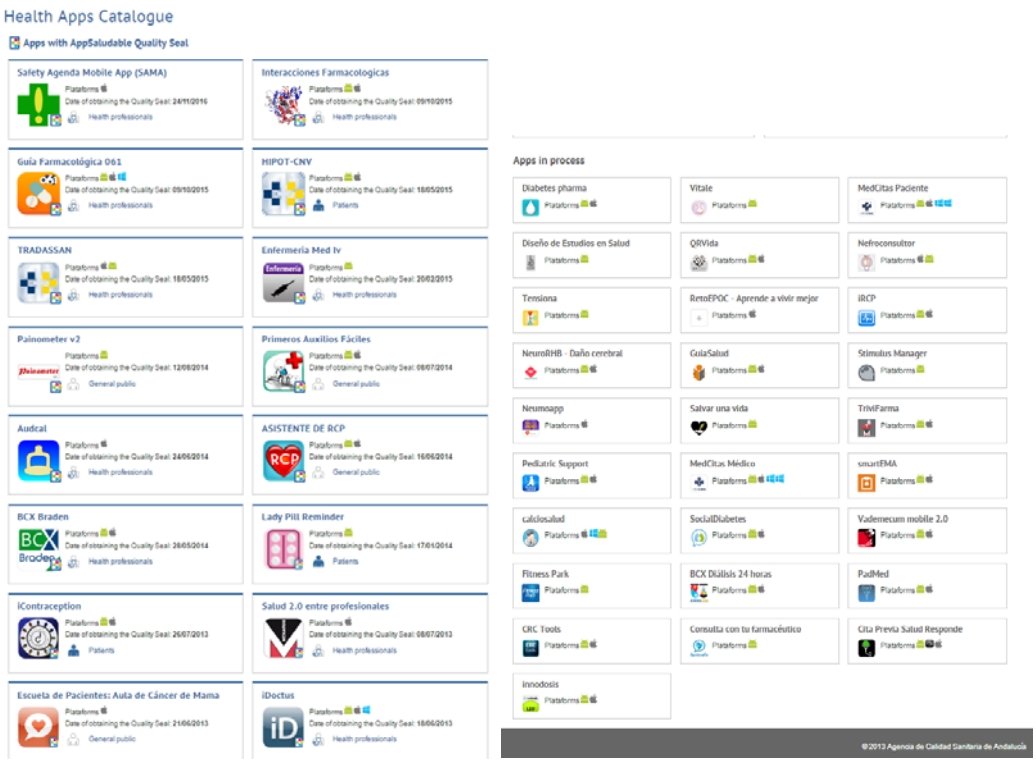
The assessment phase is based on a pass-fail methodology, where all the requirements below the 31 recommendations are divided into essential and advanced.

Compliance of all Essential requirements is mandatory in order to obtain the quality seal.

1.3 Health App Catalogue

Since 2013, more than 150 health apps have been assessed (and previously self-assessed by their own developers or people responsible for them).

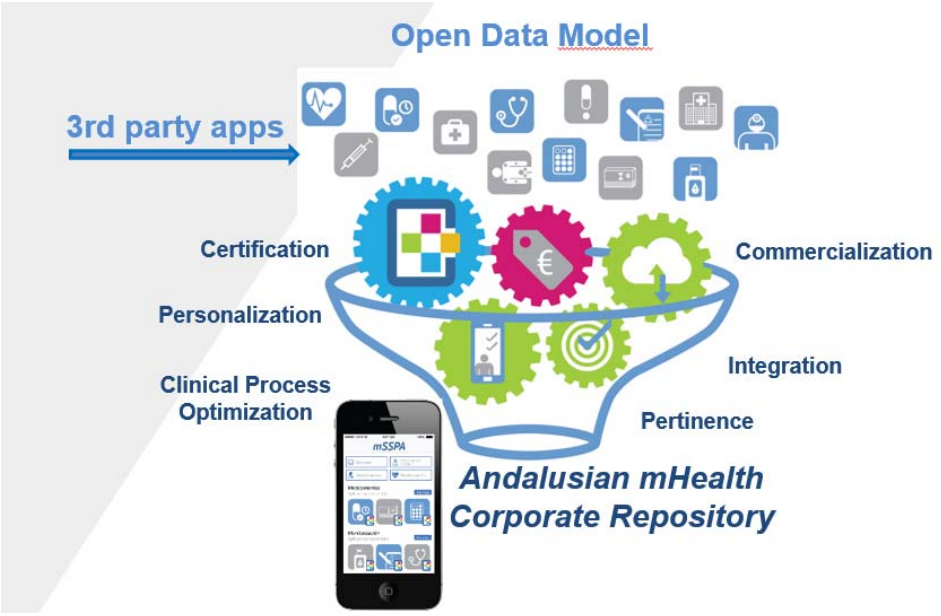
Those apps that passed the assessment are incorporated to our Health App Catalogue, where apps currently in process are also shown:



http://www.calidadappsalud.com/distintivo/catalogue

2. Integration and Personalisation of mHealth Services within the eHR

In order to enable the integration of health apps with the Andalusian eHR, we have defined the following schema:

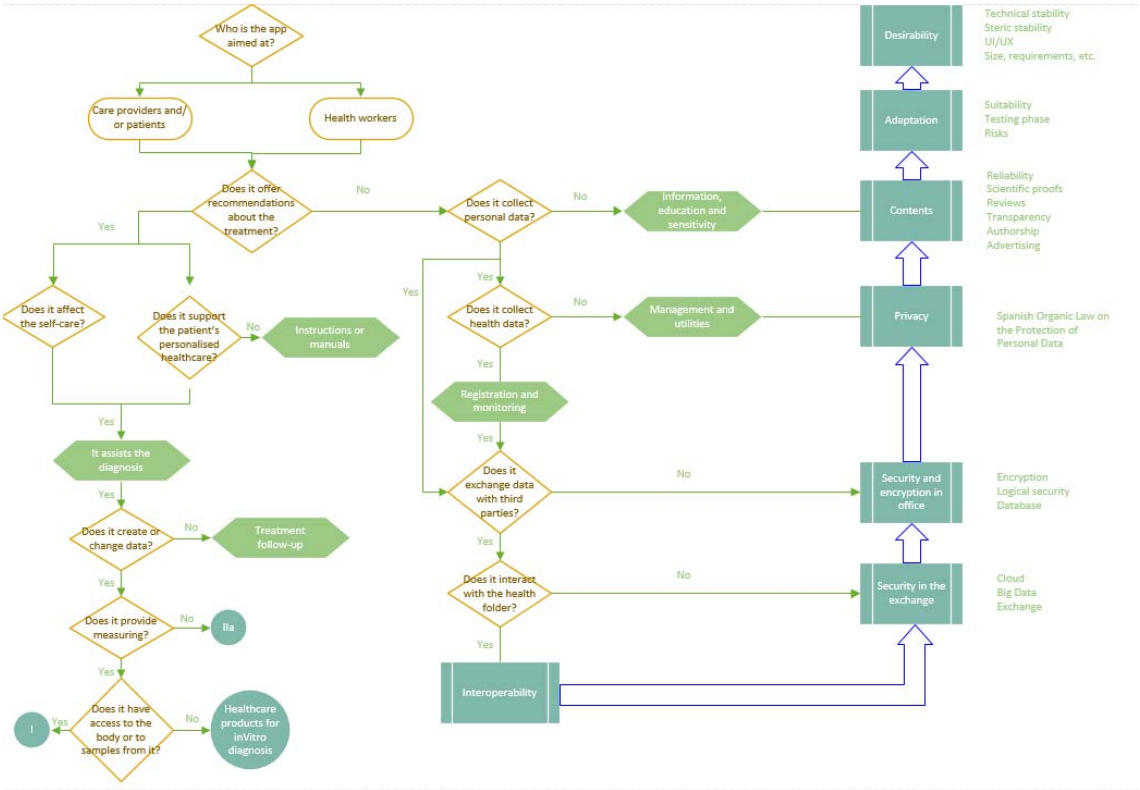


2.1 Formal Certification of mHealth Apps

Beyond the current Appsaludable distinctive, we are currently defining a formal certification process to enable the integration of health apps into the eHR in Andalusia.

A decision tree is being designed to accommodate all type of apps and to be guided through specific assessment criteria.

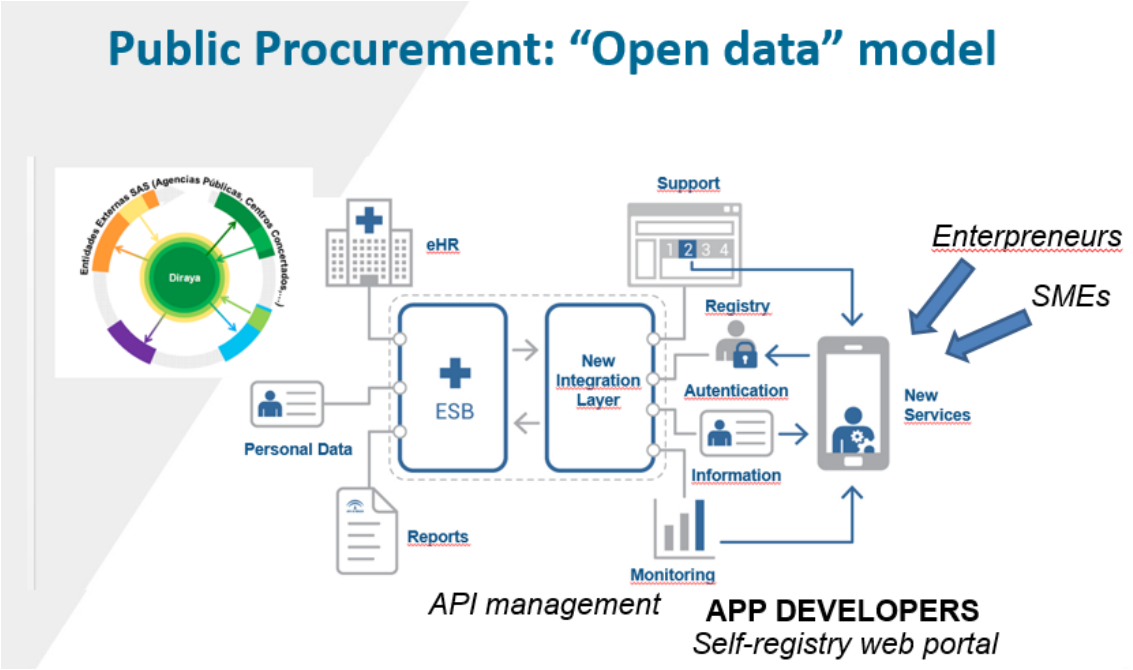
At present stage, this is the draft (to be evolved):



An expert committee is being conformed to reinforce assessment criteria.

2.2 Interoperability and Integration with the eHR

The technical architecture behind this strategy is based on an API management platform to allow third party apps to easily integrate with the Andalusian eHR, minimising complexity on technical aspects.



Some other technical aspects that need to be addressed, such as strong authentication schemas, governance model of the platform, commercialisation and reimbursement models… exceed the scope of this case use.

Annex 1 - Complete list of recommendations on design, use and assessment of health Apps

DESIGN AND APPROPRIATENESS

Appropriateness

Recommendation 1. **The health App clearly defines its functional reach and its purpose, identifying the target groups of information and the aims pursued regarding these groups.**

Accessibility

Recommendation 2. **The health App follows the Principles of Universal Design, as well as reference accessibility standards and recommendations.**

Design

Recommendation 3. **The health App follows the recommendations, patterns and directives included in the official manuals of the different platforms.**

Usability/Testing

Recommendation 4.**The health App has been tested by potential users before its availability to the public.**

QUALITY AND SAFETY OF INFORMATION

Suitability for the Audience

Recommendation 5. **The health App adapts itself to its target audience.**

Transparency

Recommendation 6. **The health App offers transparent information about its owners' identity and location.**

Recommendation 7. **The health App offers information about its funding sources, promotion and sponsorship, as well as about possible conflicts of interests.**

Authorship

Recommendation 8. **The health App identifies the authors of its content and their professional qualification.**

Information Update/Revisions

Recommendation 9. **The health App includes the date of the last revision made in the published material.**

Recommendation 10. **The health App warns of those updates which modify or influence the functioning of health-related content, as well as other sensitive data.**

Content and Information Sources

Recommendation 11. **The health App is based on one or more reliable information sources, and takes into account the available scientific evidence.**

Recommendation 12.**The health App offers concise information about the procedure used in order to select its content.**

Recommendation 13. **The health App is based on ethical principles and values.**

Risk Management

Recommendation 14. **The possible risks for patient safety caused by the use of the health App are identified.**

Recommendation 15. **The known risks and adverse events (near misses) are analysed, and the convenient actions start to be developed.**

PROVISION OF SERVICES

Technical Support/Inquiries

Recommendation 16. **The health App has a support system about its use.**

Recommendation 17. **The health App offers a contact mechanism for technical support with an assured and fixed response time.**

E-Commerce

Recommendation 18. **The health App informs about the terms and conditions on its products and services' commercialisation.**

Bandwidth

Recommendation 19. **The health App makes an efficient use of communications bandwidth.**

Advertisement

Recommendation 20. **The health App warns of the use of advertisement mechanisms and allows deactivating or skipping it.**

CONFIDENTIALITY AND PRIVACY

Privacy and Data Protection

Recommendation 21. **Before downloading and installing, the health App informs about the kind of user's data to be collected and the reason, about the access policies and data treatment, and about possible commercial agreements with third parties.**

Recommendation 22. **The health App clearly describes the terms and conditions about recorded personal data.**

Recommendation 23. **The functioning of the health App preserves privacy in the recorded information, collects express consents granted by users, and warns of risks coming from the use of online mobile health Apps.**

Recommendation 24. **The health App ensures pertinent security measures when users' health information or sensitive data has to be collected or exchanged.**

Recommendation 25. **The health App informs the users when it has access to other resources of the device, to users' accounts and to profiles in social networks.**

Recommendation 26.**The health App ensures the right of access to recorded information and the updates regarding changes in its privacy policy.**

Recommendation 27. **The health App has measures regarding minors' protection in accordance with the current legislation.**

Logical Security

Recommendation 28. **The health App neither presents no sort of known susceptibility nor any type of malicious code.**

Recommendation 29. **The health App describes the security procedures established in order to avoid unauthorised access to personal data collected, as well as to limit the access by third parties.**

Recommendation 30. **The health App has encryption mechanisms for the storage and exchange of information, as well as mechanisms for passwords management.**

Recommendation 31. **When the health App uses services from the Cloud (cloud computing), the terms and conditions of those services are declared, and the pertinent security measures are ensured.**

Recommendation 1

The health App clearly defines its functional reach and its purpose, identifying the target groups of information and the aims pursued regarding these groups.

[Appropriateness]

Purpose: Describing explicitly and objectively its target audience, as well as its aims and purpose, so that users can value the App's interest.

Requirements:

1. The purpose and aims regarding its content and services should be clearly defined.
2. The functions and their conditions should be described in detail with a clearly and accessible language.
3. It should be warned that the use of the App does not replace the health professional-patient relation.
4. The target audience should be defined in its description section, as well as it should be categorised regarding a standardised classification of health Apps.
5. The content and services should be adapted according to the target audience.

Recommendation 2

The health App follows the Principles of Universal Design, as well as reference accessibility standards and recommendations.

[Accessibility]

Purpose: Allowing everyone to use the Apps, without the need of adaptations or special designs.

Requirements:

1. The Principles of Universal Design should be followed and applied to the App.
2. Access manuals and recommendations of different platforms and makers should be followed: Android, iOS, BlackBerry, Windows Phone, etc.
3. Information about accessibility characteristics should be offered, both in the description section and in the contextual assistance sections of the App.

Recommendation 3

The health App follows the recommendations, patterns and directives on matters of design included in the official manuals of the different platforms.

[Design]

Purpose: Following established design standards in order to reach an efficient, effective, total, precise, agile and satisfactory use.

Requirements:

1. For Android Apps, "Android Design" will be used.
2. For iOS Apps, "iOS Human Interface Guidelines" will be used.
3. For Windows Phone Apps, "User Experience Guidelines for Windows Phone" will be used.
4. Likewise, makers' other directives can be used, such as "Blackberry UI Guidelines" or "Nokia Design and User Experience Library", in order to enhance users experience.

Recommendation 4

The health App has been tested by potential users before its availability to the public.

[Usability]

Purpose: Enhancing user experience since the design phase in order to minimise possible errors.

Requirements:

1. Tests are done to representative users from the target audience and the outcomes are analysed.
2. Problems detected during the tests should be corrected before the launch of the App.

Recommendation 5

The health App adapts itself to its target audience.

[Suitability for the Audience]

Purpose: Making the App understanding and use easier for users.

Requirements:

1. The App's target audience and its usefulness should be described.
2. A language in keeping with the App's target audience should be used.
3. Content and services should be developed according to the App's target audience.

Recommendation 6

The health App offers transparent information about its owners' identity and location.

[Transparency]

Purpose: Users should know who the App's owners are (person/organisation), and should be provided with the mechanisms in order to communicate with those owners.

Requirements:

1. The Health App's ownership should be clearly referenced on the general description section and on the App itself.
2. Additional information about the App's owner should be linked or shown.

Recommendation 7

The health App offers information about its funding sources, promotion and sponsorship, as well as about possible conflicts of interests.

[Transparency]

Purpose: Warning users about the origin of funding sources and about possible conflicts of interests that may have an impact on the content and services offered.

Requirements:

1. Information about funding and sponsorship sources should be linked or shown.
2. Information about possible conflicts of interests related to App's owners and to those who have some responsibility on its content and its launch should be linked or shown.

Recommendation 8

The health App identifies the authors of its content, as well as their professional qualification.

[Authorship]

Purpose: Identifying authors and responsible persons for the health App's content in order to boost its safety and credibility.

Requirements:

1. Authors/responsible persons of content should be pointed out.
2. Information about editors' and authors' professional qualification should be offered, as well as their link with organisations.

Recommendation 9

The health App includes the date of the last revision made in the published material.

[Information Update/Revisions]

Purpose: The health App ensures to its users that its content is active and updated.

Requirements:

1. The last update made on the App should be shown and the changes regarding previous version should be described.
2. The date of the revision of content has to be specified.
3. Editor's commitment with the revision of content and functions should be specified.

Recommendation 10

The health App warns of those updates which modify or influence the functioning of health-related content, as well as other sensitive data.

[Information Update/Revisions]

Purpose: Warning users of updates caused by possible errors or modifications in functioning, in health-related information, or in any other sensitive data.

Requirements:

1. Any change in functioning, health-related information or any other sensitive data should be notified to users in the description section and in the App itself.
2. In case of incident that may affect to users' health, a proactive warning system should be available in order to notify changes in the App.

Recommendation 11

The health App is based on one or more reliable information sources, and takes into account the available scientific evidence.

[Content and Information Sources]

Purpose: Publishing the scientific evidence degree and the type of sources used in each case (systematic revisions, clinical practice guidelines, peer-reviewed articles, consensual protocols, experts' consensus, etc.)

Requirements:

1. Information sources should be indicated (systematic revisions, clinical practice guidelines, peer-reviewed articles, consensual protocols, experts' consensus, etc.)
2. If the content has no renowned source, it is necessary to indicate how this content was developed, including information about its relevance and its reliability.
3. The evidence level or the used recommendation degree should be specified.
4. The scientific-technical quality of its content should be reviewed and updated according to the new available scientific evidence.

Recommendation 12

The health App offers concise information about the procedure used in order to select its content.

[Content and Information Sources]

Purpose: Declaring the degree of admission of liability regarding the selection of content, and ensuring its reliability and the reliability of its sources.

Requirements:

1. Declaring that the information or services provided does not replace the recommendation, opinion or diagnosis made by the health professional.
2. Declaring the degree of admission of liability regarding the selection and use of the content.
3. Information about the selection criteria for the content should be provided.

Recommendation 13

The health App is based on ethical principles and values.

[Content and Information Sources]

Purpose: Ensuring that aims, functions and content in the health App are based on health ethical principles and values: non-maleficence, justice, autonomy and beneficence.

Requirements:

1. Main ethical considerations should be specified.
2. Possible ethical conflicts should be identified.

Recommendation 14

The possible risks for patient safety caused by the use of the health App are identified.

[Risk Management]

Purpose: Knowing, prioritising and preventing possible risks by means of a corroborating methodology (risks matrix, FMEA, risks maps, etc.)

Requirements:

1. A corroborating methodology should be used in order to identify possible risks for patient safety caused by the use of the health App.
2. This methodology for the detection of possible risks should be described.

Recommendation 15

The known risks and adverse events (near misses) are analysed, and the convenient actions start to be developed.

[Risk Management]

Purpose: Avoiding adverse events already known thanks to their analysis and the launch of corrective actions.

Requirements:

1. A notice system for health-related risks and incidents should be established in order to allow users to inform about them.
2. Known risks and adverse events should be analysed.
3. Convenient modifications on design or procedure should be added.
4. Efficacy of adopted measures should be evaluated.

Recommendation 16

The health App has a support system about its use.

[Technical Support/Inquiries]

Purpose: Making the use of the health App easier.

Requirements:

1. Clear and understandable information about the use of the App and its reach should be provided.
2. A constantly updated guide, video or tutorial about the use of the App should be included.
3. There should be a website with additional information.

Recommendation 17

The health App offers a contact mechanism for technical support with an assured and fixed response time.

[Technical Support/Inquiries]

Purpose: Providing a contact in order to resolve incidents, problems, inquiries or suggestions about the App and its content.

Requirements:

1. The contact between responsible persons of the App and users should be clearly shown.
2. Mechanisms for the creation and sending of errors reports should be provided.
3. The information that may be sent as errors report should be always shown according to confidentiality requirements.

Recommendation 18

The health App informs about the terms and conditions on its products and services' commercialisation.

[E-Commerce]

Purpose: Ensuring transparency in the provision of products and services which includes sale and commercialisation of health information content, supplies (doctors, equipments or devices), pharmaceutical products and other health-related items.

Requirements:

1. Clear and understandable information about commercial conditions should be provided when the health App includes the sale and commercialisation of a product or service.
2. The safety in transactions where personal data are exchanged should be ensured.
3. The App should be added to a code of conduct about the provision of e-commerce products and services.

Recommendation 19

The health App makes an efficient use of communications bandwidth.

[Bandwidth]

Purpose: Avoiding an excessive data use by the health App, minimising it as much as possible and warning users when a high use of data is made.

Requirements:

1. Recommending connection to a Wi-Fi wireless network before doing a big load/download of information.
2. Every time is possible, limiting the synchronisation for big information exchanges through the network. The user will choose when to carry it out, among other options that can be previously configured.
3. Minimising the health App's size.
4. Informing about health App's size before downloading and updating.

Recommendation 20

The health App warns of the use of advertisement mechanisms and allows deactivating or skipping it.

[Advertisement]

Purpose: Users should know the health App security mechanisms and the solutions offered without prejudice of its use.

The distinction between App's content and advertisement is facilitated in order to avoid confusions.

Requirements:

1. Ads should be easily distinguishable from the editorial content through its identification with the word "advertisement", and should not be overlapped or linked to any editorial content about the same topic.
2. How to distinguish between content and advertisement should be explained in a specific section.
3. A mechanism to deactivate or skip advertisement should be provided.

Recommendation 21

Before downloading and installing, the health App informs about the kind of user's data to be collected and the reason, about the access policies and data treatment, and about possible commercial agreements with third parties.

[Privacy and Data Protection]

Purpose: The responsible persons of the App have to ensure transparency regarding the use and treatment of the collected personal data before downloading and installing the App, in accordance with current legislation on matters of data protection.

Requirements:

1. Before downloading and installing, the App should inform about if it is necessary the user's registration and what data may be collected during the App use.
2. Before downloading, there should be information about the rights on collected information, including the possible commercial use of collected data.
3. The responsible persons of the App should inform about the purpose and use of the collection of personal data.
4. Before downloading, entities that can access, collect and use this data will be identified, explaining the terms to carry out the exchange of information.
5. Before downloading, if specially protected data is collected, it will be declared expressly.

Recommendation 22

The health App clearly describes the terms and conditions about recorded personal data.

[Privacy and Data Protection]

Purpose: Ensuring the recognised principles on matters of personal data such as privacy, confidentiality, access, rectification, cancellation and objection.

Requirements:

1. In privacy policy, it is declared the conformity in accordance with the current legislation on matters of data protection.
2. Rights and duties about collected information, including possible commercial use of data, as well as access policies and use by third parties should be declared.
3. Any information exchanged with third parties aside from previously mentioned terms should be exchanged anonymously.
4. Maintenance and elimination policy about the data provided by users, as well as the exercise of rights of access, rectification, cancellation and objection, should be described.
5. The sorts of automatically collected information regarding the use of App, as well as possible data about the terminal, should be described, allowing the user to access to them.
6. The applicable law on data protection should be specified.

Recommendation 23

The functioning of the health App preserves privacy in the recorded information collects express consents granted by users and warns of risks coming from the use of online mobile health Apps.

[Privacy and Data Protection]

Purpose: The responsible persons of the health App have to ensure the rights to honour and privacy.

Requirements:

1. Warnings of the risks coming from the use of online mobile Apps should be shown to users.
2. Personal information should be collected, stored and exchanged according to security standards which ensure its confidentiality all the time.
3. The health App's owner must have an express consent granted by the user before the collection of sensitive or specially protected data which will be stored in encrypted form.
4. User's express consent is required in order to use their personal information for purposes other than those it was collected for.

5. A mechanism for users to control the automatic collection of navigation data and App use should be provided.

Recommendation 24

The health App ensures pertinent security measures when users' health information or sensitive data has to be collected or exchanged.

[Privacy and Data Protection]

Purpose: Protecting especially sensitive information provided during the use of the health App.

Requirements:

1. The App should collect especially sensitive health information about users in accordance with the applicable law.
2. Convenient encryption mechanisms should be used both for the storage and the exchange of health or especially sensitive information.
3. The App should ensure to its users the access to health information, identity and the record of accesses by third parties.
4. Anonymity of collected information in any other situation of information exchange with third parties aside from what it is specified in the privacy policy should be ensured.

Recommendation 25

The health App informs the users when it has access to other resources of the device, to users' accounts and to profiles in social networks.

[Privacy and Data Protection]

Purpose: Controlling access to data outside the health App without user's express consent.

Requirements:

1. If mobile network resources are used (bandwidth, SMS, MMS, mails…) the reason why they are being used should be indicated.
2. If terminal resources are used (Bluetooth, camera, GPS, agenda, calendar…) the purpose of their use should be indicated, as well as the profiles used for the user's identification.
3. If access to user's accounts and profiles in social networks is provided, the user should be notified about it.
4. The estimated consumption of resources with economic cost made by the App should be notified.

Recommendation 26

The health App ensures the right of access to recorded information and the updates regarding changes in its privacy policy.

[Privacy and Data Protection]

Purpose: Allowing users to know the terms on use of collected information by the health App, as well as allowing them the exercise of their rights at any moment.

Requirements:

1. A notice mechanism should be provided in order to inform users about any change in the privacy policy, allowing them to renew the consent over their data.

Recommendation 27

The health App has measures regarding minors' protection in accordance with the current legislation.

[Privacy and Data Protection]

Purpose: Safeguarding minors' safety and privacy in the use of health Apps.

Requirements:

1. Clear information about available content for users should be provided according to age groups and suitability.
2. An age verification process (automatic or self-reported) should be provided in order to control the access to content restricted to minors.
3. Request, collection, use or revelation of minor's information should not be allowed unless a verifiable parental consent is granted.
4. The App's owner will remove all minor's information collected without a parental consent, including information exchanged with third parties.
5. The health Apps for children must provide the option with which parents/guardians may be able to avoid the automatic revelation of their children/minors' location.

Recommendation 28

The health App neither presents no sort of known susceptibility nor any type of malicious code.

[Logical Security]

Purpose: Preventing loss or dissemination of user's information due to susceptibilities or virus, Trojan horses or any other malicious agent's infection through the health App.

Requirements:

1. When a scanning of the App is done, neither malicious software nor code should be revealed.

Recommendation 29

The health App describes the security procedures established in order to avoid unauthorised access to personal data collected, as well as to limit the access by third parties.

[Logical Security]

Purpose: Offering transparent information about protection measures and techniques provided by the health App in order to ensure privacy and confidentiality.

Requirements:

1. The access to sensitive information should be restricted to the essential staff able to govern and manage it.
2. Information about logical, physical and technical security mechanisms used in order to protect information from unwanted accesses should be provided.

Recommendation 30

The health App has encryption mechanisms for the storage and exchange of information, as well as mechanisms for passwords management.

[Logical Security]

Purpose: Avoiding risks associated with interception of health information or other sensitive data stored in the device and/or sent through public data networks.

Requirements:

1. A locking mechanism for the access to personal information by PIN, password or another protection system should be provided.
2. Passwords should be stored and exchanged in encrypted form.
3. A reliable system for remembering passwords should be provided.
4. Procedures for the prevention of access to information by third parties should be provided, such as session expiration control.

Recommendation 31

When the health App uses services from the Cloud (cloud computing), the terms and conditions of those services are declared, and the pertinent security measures are ensured.

[Logical Security]

Purpose: Offering information to users about data cession to third parties and offered guarantees.

Requirements:

1. Nature, terms and conditions of the services available in the Cloud should be clearly declared.
2. Security mechanisms and standards accomplished by the services available in the Cloud should be described.
3. A procedure for access and management of information stored in the Cloud should be provided by users.