



PGEU GPUE

**Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union
Européenne**

Public Consultation on the Green Paper on mHealth

PGEU RESPONSE

Public Consultation on the Green Paper on mobile Health – PGEU Response

- 1 PGEU is the European association representing community pharmacy. Our members are the associations and chambers of pharmacists from 35 European countries.
- 2 We welcome the opportunity to comment on the public consultation on the Green Paper on mobile Health.

Key Points

- **Public confidence in the protection of data generated by mHealth is key to its successful deployment. This requires both data minimisation and robust approaches to the granting of consent by patients.**
- **The Commission needs to develop its work on Guidelines in connection with the lifestyle app/Medical Device distinction. Review processes for apps should be encouraged.**
- **A number of mHealth solutions are being developed by community pharmacists across Europe.**
- **More work needs to be undertaken to better understand the barriers to implementation and take up of mHealth.**

Data Protection

- 3 The protection of data (including the security of health data) is of paramount importance to both patients and the healthcare professionals with whom they consult. With the proliferation of mobile devices and their widespread use by the general public in a non-health context, it is important to appreciate the added significance of processing health data, which is probably the most sensitive and personal type of data one can process.

The potential to exploit health data is significant. To take one example from the pharmacy context, transfer of information on recent medication changes or additions to drug therapies could be made from an mHealth solution to the patient medication record in the pharmacy, thus allowing the pharmacist to identify any potential drug interactions or inappropriate prescribing. Physiological recordings taken by the mHealth solution (e.g. blood pressure, blood glucose, cholesterol etc) could be transferred to the patient record in the pharmacy in order for pharmacists to provide appropriate advice to both patients and to their prescribers and ultimately improve patient safety and quality of care.

Consent from patients is crucial to the ethical use of data, and the prevention of abuse. There is a risk however that where patients download apps, they are not properly informed about the potential use to which their data may be put. In addition, requests for consent can potentially be hidden in the downloading process. Such requests should be part of a discrete process with requisite information given in standardised form.

It is essential that the form of consent is such as to minimise potential for misunderstanding. For example, online shoppers are often asked to tick boxes to show they have read terms and conditions, but few actually read them – data consent should not take this form. Consent must always be opt in, and the default settings of apps must be on a refusal of consent basis – in other words, the principles of privacy by design and privacy by default are, we would argue, particularly relevant to the use of mobile apps, and need to be factored into not only the design but also the downloading process.

Developers should also keep in mind when considering questions of “data minimisation”, “data protection by design” and “data protection by default” in that the end user may be a healthcare professional.

Big Data

- 4 Big Data amplifies the general risks and general benefits for the use of health data. The potential benefits are such that, arguably, failing to exploit Big Data potential is in itself contrary to broader societal interests. However, the risks of misuse are huge. For example, anonymisation is key to the ethical use of Big Data, but anonymisation processes vary in robustness and quality.

As the Green Paper notes, data minimisation is particularly problematic in a Big Data context given both the potential richness of data and its various possible uses. However, some caution is required –Big Data for health is still in its infancy, and the approach to regulation should be such as to help realise the positive potential of Big Data.

The EU Legal Framework

- 5 Evidence suggests¹ that still, the majority of health apps fall into the lifestyle and wellbeing category. It is also the case that some apps are more appropriately considered as medical devices (such as those which suggest treatment options). Drawing the line between medical devices and lifestyle apps is likely to be highly problematic, particularly give the dynamism of the market (the market is likely to move faster than rules in this respect.)

In principle however, full licensing processes for genuine lifestyle apps is likely to be highly expensive and cumbersome, and will surely discourage development. It is also in the nature of software applications and the internet that strict licensing is difficult to enforce. A Guidelines based approach, updated to reflect market changes, and based on specific examples of device type apps and ‘mere’ lifestyle apps would be a useful pragmatic response. The approach of the Food and Drug Administration in the US is helpful in this respect. Over time, a recognised typology of apps is likely to emerge which will be helpful to health professions, manufacturers and regulators, although it must be acknowledged that the de-centralised EU approach to devices regulation makes this more complicated.

Comprehensive certification covering all apps and including efficacy considerations is likely to be impossible given the range and number of apps available. Review procedures based on basic criteria such as legal compliance are however an attractive option, and could provide reassurance to the public.

¹ IMS, 2013. Patient Apps for Improved Healthcare: From Novelty to Mainstream. IMS, Accessed [30 Jun 2014]. Available from: <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=e0f913850c8b1410VgnVCM10000076192ca2RCRD>

The NHS England health apps review process² allows health apps to be reviewed by a team of healthcare professionals and safety experts to ensure the apps comply with data protection laws, trusted sources of information and safety standards.

The European Code of Practice for Telehealth Services³, (which was produced by the partners of the “TeleSCoPE Project” as part of an EU project under the Commission’s eHealth Action Plan 2012-2020) provides a quality benchmark against which telehealth services can be assessed and accredited. Whilst these are not strictly certification schemes, they are perhaps a good place to start, and as such the PGEU would also recommend that any certification or review board for mHealth apps comprise at least one community pharmacist to enable truer reflection of demographic of healthcare professionals collaborating with patients with mHealth solutions.

- 6 In order to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing, healthcare professionals should be trained to advise patients in an unbiased way on the options available on the market (e.g. highlighting any certification schemes and regulation, and their significance). Healthcare professionals, such as community pharmacists (who are readily and easily accessible in the primary care and community settings), are perfectly placed to provide this service with additional follow-up to their patients, potentially as part of a state / health service / co-payer / technology innovator funded public health service.

mHealth role in healthcare systems and equal access

- 7 It is worth stressing however that as yet, those most in need of e.g. help to improve medication adherence are those least likely to be smartphone users. Additionally, reliance on mHealth as an efficiency driver must not prejudice those who prefer more traditional forms of care, and of course must be based on solid evidence of satisfactory health outcomes.
- 8 We provide examples in Annex 01 of pharmacy lead mHealth solutions within the EU’s healthcare systems, as well as initiatives in pilot phase which are earmarked for inclusion in health systems in the future.
- 9 The PGEU acknowledges the lack of good practices in the organisation of healthcare to maximise the use of mHealth for high quality of care (i.e. clinical guidelines). However, PGEU believes that mHealth solutions incorporated into clinical guidelines may provide positive benefits to both patients and healthcare professionals alike by reducing time consuming bureaucracy and accessing of health records and collecting data during face-to-face consultations. There is also the advantage of collecting telemetry of physiological measurements more frequently when it is performed remotely (i.e. the patient not needing to attend clinic as often). It is essential to remember the significance of face-to-face care which is traditionally provided in healthcare settings and the importance that patients place on this type of interaction with a healthcare professional.

² NHS England, 2014. NHS Choices Health Apps Library Review Process. NHS England, London. Accessed: [30 Jun 2014]. Available from: <http://apps.nhs.uk/review-process/>

³ TeleSCoPE, 2014. V4 Standard European Code of Practice for Telehealth Services. Accessed [01 Jul 2014] Available from: <http://www.telehealthcode.eu/>

- 10 The potential for mHealth to constrain or curb healthcare costs has been demonstrated by researchers at the Netherlands Institute for Health Services Research who published a review on electronic patient medicine reminders and concluded that electronic reminders, (such as text messages, pagers and audiovisual solutions) improved medicines adherence by 14%⁴. Given that the cost of wasted medicines, poor medication adherence and the associated consequences, these initial results seem promising. It has been estimated that failure to adhere to prescribed regimens alone contributes to 200,000 premature deaths every year in Europe, costing the healthcare system approximately €125 billion.⁵ With any intervention in healthcare, it is essential that cost-effectiveness is achieved and mHealth solutions should be no different. There should be no drive to invest in mHealth solutions without them first being proven to be effective.
- 11 At EU level, policy action could focus on funding and creating an mHealth network which could be launched as one of the offspring from the eHealth network. It could allow exchange of good practices, participation from relevant stakeholders and address some of the technical and regulatory issues surrounding mHealth solutions. Once again the PGEU considers it vital to remember the importance of maintaining face-to-face healthcare and mHealth solutions should not replace such interactions, but complement them.

Interoperability

- 12 Following on from the last point, one of the technical solutions which could prove difficult to address would be that of semantic, technical and organisational interoperability. Considering that mHealth solutions are tipped to continue proliferating over the coming years, that there are a multitude of platforms for app developers to utilise and that there is a strong desire to increase pharmacist access to patient medication and medical records, the interoperability of mHealth solutions with existing patient medical records and pharmacy medication records is an important issue to explore. This is of course in the context of agreement with the patients, through an explicit, opt-in and informed consent process. It is essential that healthcare professionals, including community pharmacists are consulted during the development of mHealth solutions. This group forms one of the vital stakeholders along with the developers, patients and health system administrators.

Reimbursement Models

- 13 The PGEU believes that recommending, prescribing and collaborating with / monitoring patients with mHealth solutions should be a reimbursed service for community pharmacists. Given the excellent accessibility of the community pharmacist, a healthcare professional at the heart of each community, in the workplace and in rural areas, and the pharmacists' existing repertoire of activities (in pharmacovigilance, managing side effects, adverse reactions, interactions, dose adjustments, therapeutic recommendations, providing information to patients and public health promotion) the PGEU believes community pharmacists are well placed to deliver such a funded service. Two examples of reimbursement models are set out in Annex 02.

⁴ Vervloet M, Linn AJ, van Weert JCM, de Bakker DH, Bouvy ML and van Dijk L. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. 2011. J Am Med Inform Assoc doi:10.1136/amiajnl-2011-000748

⁵ Consejo General de Colegios Oficiales de Farmacéuticos, 2013, Adhiérete. Accessed [30 Jun 2014] Available from: <http://www.portalfarma.com/profesionales/investigacionfarmacia/adhierete/Paginas/Programa-Adhierete.aspx>

- 14 From a community pharmacist perspective, a specific topic for EU level research & innovation and deployment priorities for mHealth would be adherence and polypharmacy related applications.

More generally, better understanding the use of mHealth solutions for elderly patients (the biggest consumers of healthcare) is essential – we risk investing in new products for which there is little immediate benefit because we do not adequately understand the barriers to implementation (which may be practical and behavioural, not merely organisational). We need to better understand how the elderly might access and use mHealth, what kind of features are more likely to be successful than others, and how mHealth solutions can be deployed on a wider scale. Technical potential is sometimes far removed from the actual ability to integrate technical solutions into health systems.

Annex 01

Examples of mHealth from France:

"Observia"

"Observia" is a text message service patients can subscribe to for free when advised to by a health professional which sends texts with hygiene and nutrition advice related to the particular disease area (e.g. hypertension, diabetes, respiratory failure). The service also provides alerts to improve medication adherence, reminders for appointments, vaccinations, repeat prescriptions, invitations to contact other patients suffering from the same illness and also safety alerts sent by the pharmacist (e.g. pollution and pollen indices, medicine recalls). Patients can manage their account by phone or on the Internet.⁶

"DO-Pill"

"DO-Pill" is a smart electronic pill-box that "brings the expertise of the pharmacist back home". When the pharmacist receives a prescription, they register its content on the pharmacy computer, which is connected via the internet to the pill-box. The computer updates the data while the pharmacist fills the compartments of the pill-box. When the patient needs to take their treatment, an alarm sounds and the relevant compartment of the pill-box lights up. Another alarm also sounds if the patient opens the wrong compartment. The pharmacist is informed when the patient opens a compartment, whether is it in line with the regimen or not. The pill box is available on prescription. "DO-Pill" is currently used in three French projects as a support tool for improving adherence specifically for patients who have recently had a kidney transplant, who suffer from epilepsy and children and teenagers suffering from leukemia.⁷

⁶ L'Ordre national des pharmaciens de France, 2014, (<http://www.ordre.pharmacien.fr/>) (personal communication) and la Société Observia SAS Accessed [30 Jun 2014] Available from: (<http://www.observia.fr/Professionnels-de-sante>)

⁷ L'Ordre national des pharmaciens de France, 2014, (<http://www.ordre.pharmacien.fr/>) (personal communication) and Pharmagest Interactive, 2014, Accessed [30 Jun 2014] Available from: (<http://www.pharmagest.com/>)

Example of mHealth from Portugal:

“iFarmácias”

“iFarmácias” is an app with a location map of all Portuguese pharmacies allowing patients to find the nearest one, check if it's open and, if it's a registered pharmacy with this app, the patient will be able to communicate with the pharmacy by sending the list of medicines they need. The app will also calculate the price of the medicines for the patient. The patient can then receive feedback from the pharmacy when all medicines have arrived or provide information on home delivery. Pharmacies need to register with the app and have dedicated back-office software to manage reservations and mobile requests.

The patient still needs to meet the usual criteria regarding prescriptions, payments and receipts. The app can also calculate when a given medicine is due to run out and will warn the patient that they need to obtain a new prescription. This app also has a module for entries on common health parameters such as height, weight, body mass index (BMI), blood pressure, blood sugar and cholesterol values. This information can then be shared with health professionals and is protected with financial-app-level security features.⁸

Examples of mHealth from Spain:

“Adhieréte”

“Adhieréte” is a research program to evaluate the impact of new technologies in the improvement of adherence to treatment in polymedicated and non-complying elderly patients with chronic disease, increasing the healthcare systems’s sustainability through community pharmacy initiatives. The project assesses the value offered by several supporting tools including ICT tools and Personalised Dosage Systems (PDS) in improving adherence. The project also assesses the impact of electronic prescriptions on improving adherence in terms of efficiency and effectiveness.

Out of the five patients (per pharmacy) included in the study, two will receive the Personalised Dosage Systems (PDS) service, two will receive telepharmacy services and one patient will receive PDS combined with a remote alert system. Data will be collected in an electronic Data Collection Notebook and the information recorded will be periodically reviewed by the study monitor.

A web based platform will be also used to allow medication management and monitoring which sends notifications, reminders and ad hoc messages to the patient from the pharmacist. The application will allow the patient or caregiver, via a cell phone application to be alerted of any non-compliance with medication regimens, registering such incidences, thus offering a greater control of adherence, and an increase in communication between the pharmacist and the patient’s home.

Results obtained from a pilot study conducted between 2009 and 2010 in pharmacies in Azuaga (Badajoz) show that after pharmacists’ intervention, patient adherence improved from 41.2% to 70.6%³.

⁸ iFarmacias, 2014, Accessed [30 Jun 2014] Available from: <https://www.ifarmacias.com/landing/>

“BOT PLUS 2.0”

BOT PLUS 2.0 App is an application for mobiles developed by the General Pharmaceutical Council of Spain, for healthcare professionals, enabling them to quickly and easily access information on medicines from a mobile reference source.

This tool supports pharmacists and other professionals in their daily healthcare practice, providing a source of official, independent, contrasted, reliable and constantly updated information, contributing to the safe use of medicines. The app allows users to easily retrieve information on medicines and active ingredients for human use authorised and marketed in Spain. Such data includes that relating to medicines financing, dispensing, conditions of use and interactions.⁹

Example of mHealth from Sweden – FASS

“FASS”

“FASS” is an IT solution for the public display of stock levels in Swedish pharmacies. The aim of this tool is to enable easily accessible, real-time nationwide information on pharmacy stock levels for patients as well as for pharmacy and health care staff, through a trusted and established channel.

As well as the standard geopositioning information and contact details of respective pharmacies, the app also displays the following stock information:

- In stock
- Few in stock
- Not in stock
- Substitution available
- Not in stock - can't be ordered from distributor

⁹ Consejo General de Colegios Oficiales de Farmacéuticos, 2013. BOT PLUS 2.0. Accessed [30 Jun 2014]
Available from: <https://botplusweb.portalfarma.com/>



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The use of such an app obviously has implications for patient empowerment and tackling the issue of medicines shortages.

¹⁰ Sveriges Apoteksförening/SA Service AB, 2014 (personal communication) and Läkemedelsindustriföreningens Service AB, 2014. Accessed [30 Jun 2014] Available from: www.fass.se

Annex 02

Example of mHealth – UK NMS – fee for a service, focus on telephone consultation (on a mobile), an example for progression

In the UK the New Medicines Service (NMS) provides support for people with long-term conditions who have been prescribed a new medicine to help improve their adherence. This service, provided by pharmacists is initially focused on particular patient groups and conditions, such as those receiving medication for diabetes, hypertension, asthma and anticoagulant / antiplatelet medication. Patients are recruited at the point of dispensing, counselled on any relevant points about the new medication and provide consent to participate in the service. Within two weeks either a face-to-face (in-pharmacy) or telephone consultation takes place where the pharmacist conducts a semi-structured interview in order to identify any problems, side-effects, concerns or non-adherence to the new medication. At this point referral can be made to the patient's GP if required or appropriate advice can be provided by the pharmacist and a date arranged for a final consultation within a two week period. In either case, this interaction with the patient is also an opportunity for the pharmacist to provide dietary and healthy lifestyle advice to the patient. The service continues to be funded by the National Health Service and after the first 18 months of provision a total of 236,408 NMS cycles were completed representing a total of 224,554 patients.¹¹

Example of mHealth – France Telemedinov – further example for progression and expansion in to mHealth solutions

In France, telemedicine projects are supported by Regional Health Agencies. An example of good practice is the Telemedinov project in the Nantes region (Pays de la Loire), where a teleconsultation service hosted in community pharmacies aims at monitoring both acute and chronic conditions (angina, otitis, diabetes, heart failure, hypertension, dermatological conditions). An assessment showed that the service model significantly reduced costs while offering the same clinical outcomes.

The economic model is based on the creation of value through new interprofessional cooperation schemes, secured shared access to information (medical and pharmaceutical records), secured e-prescription and electronic transmission of invoices.

As such, the costs for pharmacies providing the service are reimbursed by the Regional Health Agency and National Health Insurance. They are as follows: rental of video and measurement equipment and use of tests (€450), ADSL subscription/connection (€150) and 12% FTE technician salary (€310), which makes a total of €910 entirely reimbursed. Pharmacies treating more than 40 patients in a month receive an additional €170 compensation. A reimbursement model such as this could be developed and expanded for other mHealth solutions, reducing costs and achieving positive clinical outcomes.¹²

¹¹ Pharmaceutical Services Negotiating Committee. New Medicines Service (NMS). 2014. PSNC, London. Available from www.psn.org.uk/services-commissioning/advanced-services/nms

¹² L'Ordre national des pharmaciens de France, 2014, (<http://www.ordre.pharmacien.fr/>) (personal communication) and Telemedinov, 2014. Accessed [30 Jun 2014] Available from : <http://www.telemedinov.fr/>