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Assessing If Patients Would Benefit From Electronic Patient Information Leaflets (ePils)

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Assessing if patients would benefit from Electronic Patient Information Leaflets (ePILs).

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Abstract
The importance of the patient information leaflet (PIL) is underlined by the fact it is the only mandatory information that patients in Europe are legislated to receive with their medicines. Issues with the PIL in its current paper format have been well documented and in recent years there has been a push to move from these paper leaflets provided in the medicine carton to the information being made available as an electronic PIL (ePIL).

This paper explores the potential negative and positive consequences of ePILs and their impact on patients. In a survey of almost 600 people it was shown that people's willingness to embrace the ePIL is very much age dependent. The survey also demonstrated that more people than expected are reading the paper PILs while it also indicated that there is higher likelihood of people reading the PIL based on the medication type, prescription versus over the counter and the frequency the medication is used by the patient.

There are positives and negatives to both the ePIL and the paper PIL. When the two are compared, it is the electronic version that has the greater number of benefits for patients. The main benefit of the electronic version is that it ensures that the most current version of the PIL is available to patients – whether or not patients are aware that they are not always getting the most current version of the PIL was not assessed in this study. This paper assesses the benefits and negatives of electronic PILs versus the current PIL.

Additionally, interviews with industry and regulatory subject matter experts suggest some best practices that might be considered to ensure maximum benefit for patients in the use of ePILs.

Introduction

Patient Information Leaflets (PILs) are commonly referred to by a number of terms including; patient inserts, package inserts (PI), packaging leaflets, package leaflets (PL), package information leaflet, patient package insert and consumer medicine information to name but a few. Irrespective of the name used it is the printed material often found folded up or in booklet format, that in the Europe Union (EU) should come with every medicine, be it prescribed by a doctor or over the counter. As per Article 1, Point 26 of Directive 2001/83/EC, the definition of a patient information leaflet or package leaflet is that it is 'a leaflet containing information for the user which accompanies the medicinal product' (Directive 2001/83/EC, 2001). The PIL must be written in accordance with the summary of product characteristics (SmPC) and has to be aligned with Article 59 of Directive 2001/83/EC. The SmPC is required to provide professionals prescribing medication a 'neutral, objective source of information about products' (Van Dijk, 2014). The key point of the SmPC is that it is information for professional use not patient use, yet it is the source of the material that is then utilised in the PIL provided to patients. The foundation of the PILs information being a technical document, may account for some of the issues cited with the PIL such as the use of overly technical language.

To be effective a PIL must be noticed, read, understood, and retained and should contain the most current information. At present, patients may not always have the most current PIL version in their medicine carton. New variations to PILs are regularly approved by health authorities, this PIL version then becomes the effective version and is distributed with medicines leaving the site of manufacture. Issues can arise if previously released and distributed medicines still contain the old version of the PIL.

Health Literacy is defined as having the ability to obtain, understand, act on and communicate health information (College, 2008). Low health literacy is quite common and is related to amongst other things, literacy level. In Ireland approximately 18% 'or one in six, Irish adults are at or below level one) on a five level literacy scale (NALA, 2012). In Europe, this figure rises to one in five adults, which equates to approximately 20% of Europe's population between 16 and 65 years (ELINET, 2015). Plain English is the use of short, clear sentences and everyday words and avoiding the use technical jargon. The use of plain English is particularly important in

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assisting people's comprehension of the PIL. One health authority who has put an emphasis on the use of plain English is Health Canada. In their guidance they suggest using 'the simplest, most common words possible', the reason being that it ensures that the information being provided is 'clear, concise and easy to understand for the intended audience' (Health Canada, 2014a). It is specified in Health Canada's guidance that the vocabulary used in PILs is appropriate for 'Grades 6-8 reading level' (Health Canada, 2014b), this equates to approximately an 11-14 yearold age group.

When it comes to reading PILs, people are highly selective. In the September 2020 issue of Regulatory Rapporteur, Dr. Theo Raynor is a professor at Leeds University, who has critically researched the impact of European legislation on medicine leaflets, he is considered a leading figure in the European consumer medicines information movement and views having an informed patient as being a goal in itself. (School of Pharmacy University Wisconsin, 2013). Dr. Raynor has been involved in many studies and articles on PILs. In a September 2020 interview published in Regulatory Rapporteur he stated that 'people tend not to value pieces of paper that fall out of boxes' (Stewart, 2020). David Sless of the Communication Research Institute lists some common characteristics of a PIL reader in his book 'Writing about Medicines for People: Usability Guidelines for Consumer Medicine Information' (Sless, 2006). Some of these characteristics are listed in Table 1.

#	Details
1	Readers rarely if ever read the entire document from start to finish.
2	Readers are reluctant to read more than they think they need to read.
3	If they know, or think they know how to use a medicine or product, they are unlikely to consult the PIL until a problem occurs.
4	Good layout and structure make a document easy to read. A cluttered, small font size poorly printed document is less likely to be read.
5	Reader's regularly scan documents to find what they want or need.

Table 1: Common Characteristics of a PIL reader (Sless, 2006)

Other studies have been performed to assess patients' attitudes to the PIL. One particularly informative study, performed in 2016 in South-East Sweden, determined that approximately 50% of respondents read the PIL sometimes, while approximately 35% stated that they always

read the PIL (Hammar, 2016). A second study, performed in Germany in 2005, assessed from a patient's perspective, the importance of different package insert issues (Fuchs, 2005). The most common issue selected by survey participants was that package inserts are difficult to understand, with 50% of respondents selecting this option. Other issues listed in this survey included that they are too extensive and too difficult to read. The same 2005 survey found that only 16% of participants were satisfied with the current format of the PIL, while 76% felt that the leaflet should only contain the most important information (Fuchs, 2005). Dr. Theo Raynor believes that the electronic provisions for package insert information will change people's attitudes to PILs (Stewart, 2020).

In January 2020, the European Medicines Agency (EMA), along with the Heads of Medicines Agencies (HMA) and the European Commission (EC) published a report called 'Electronic product information for human medicines in the EU: key principles' (EMA-HMA-EC, 2020). The collaboration report states that 'developing an electronic format is the most pressing priority of the actions from public-health perspective', the reason being is that 'it will facilitate timely access to up-to-date information' (EMA-HMA-EC, 2020). The report calls for the introduction of an electronic product information (ePI) be introduced. This ePI will see patient information that is currently in a paper format being made available online – it will be an extended and complimentary method of delivering the information to patients, as it will the information will continue to be delivered via paper also. In many ways this ePI has the characteristics of an ePIL that are discussed in this paper, but both terms are used because there are some differences in the two concepts.

The ePI will not be a replacement for the current format and it 'is intended to expand the formats' rather than 'remove or substitute', the reason they state for this is that the 'paper PL is particularly important for patients / consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access' (EMA-HMA-EC, 2020).

The major benefit to introduction of the ePI is 'that increased numbers of people will be able to access it and will wish to access it' (Stewart, 2020), a further positive according to Dr. Raynor is 'that app developers will be able to incorporate information from package leaflets into their

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applications' (Stewart, 2020). This is just one example of the benefit of the PIL being online – electronically it will be searchable so users will be able to search key words, while viewing the PIL on a device means patients will be able to increase the font size or viewing window.

The Interviews

Interviews with regulatory/industry experts were included in this assessment to determine these expert's opinions on the ePIL versus the paper PIL, and which is the more effective method of delivering information to patients. One of the experts had previously worked as Head of Over-the-counter Medicines at Therapeutic Goods Administration (TGA), Australia and is currently a director of a regulatory consultancy firm, based in Australia. The second expert is employed in the Health Products Regulatory Authority (HPRA), Ireland.

As Australia already utilise an electronic PIL, or Consumer Medicine Information (CMI) as it is named, the first expert was able to offer insight on its use in Australia. The negative of the paper leaflet that the expert highlighted was the font size being too small, but noted the positive of a paper PIL is that it is the right information for the medicine supplied. In order to ensure patients are accessing the correct CMI, medicines that require CMIs often include a QR code on the packaging that can be utilised by patients by means of scanning it with their smart phone or other suitable device and it will bring them directly to the current CMI.

The key benefit that the second expert envisioned with the introduction of the ePIL was that it would ensure the most current version was the one available to patients. He also cited the technological possibilities that having the PIL in electronic format may provide. The drawback this expert noted with a move to an ePIL was the potential to isolate those that do not have the technology to access it online.

The second expert's interview highlighted a major gap in the communication being provided to patients, in that patients are sometimes dispensed medications without the PIL. This arises when the pharmaceutical company, complying with the legislation supplies a PIL with the finished product. However, if the finished product is a bulk supply antibiotic capsules, for example, one PIL is supplied but several patients will be dispensed their prescription from this supply and more often than not the PIL is not received by the patient. There is also a process

called split or broken packs where the blister may contain ten tablets but if a prescription is only for seven tablets, the pharmacy will cut the blister to the prescribed quantity blister, meaning it may not get delivered in its original box and thus the PIL is not supplied. This issue is an area where there was extraordinarily little information available to assess its impact, as part of the literature review. Despite the lack of information of the, the author came across two examples during the course of this assessment where they were dispensed medicines without PILs, one was a capsules dispensed from a bulk supply into a green plastic container and the other was a blister removed from its original pack, cut to dispense the prescribed quantity and distributed to the patient in a small clear plastic sample bag.

Interviews were also carried out with a number of community pharmacists as they are well positioned to understand the common queries patients have with the PIL in its current format. Two of the pharmacists were based in Ireland while one was based in London. All three pharmacists were aware of the practices of dispensing medicines from bulk supplies and splitting or breaking blister packs, the difference however was that the London based pharmacist always printed and issued a PIL, as was the policy of the pharmacy where she was employed, while the pharmacists working in Ireland did not typically supply a PIL when dispensing medicines without their original packaging. Both the Irish based pharmacists said that it would be a very rare occurrence that a patient would come back to the pharmacy to request a PIL, if they hadn't been provided one originally. With regards to the positives that ePILs could bring, the pharmacist in London felt the possibilities of increasing languages would be a key factor in ensuring the PIL reached more people. The area in London in which she was based has a large number of patients who English was not their first language and were reliant on family members to give them information on their medicines. All three pharmacists felt access to the PIL would improve by it being online but were concerned if it was fully online that people of a certain age would not be able to utilise the ePIL – this aligns with the 'low digital literacy statement' made in the EMA-HMA-EC report (EMA-HMA-EC, 2020).

The Survey

The survey was generated and completed using www.surveymonkey.com. Ensuring a diverse a age group was captured for this survey was critical to the author, particularly in gathering the

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opinions of those over the age of 60, as they are the least likely to be active on social media and are the most likely to be taking medications. Data was collected using email, various social media platforms such as Instagram and LinkedIn. To increase the number of respondents in the +60 age categories paper copies of the survey were distributed to a local ballroom dance studio, that has several members in this age category and a retiree's association was also contacted. Lindemann's 2019 benchmark study on survey responses states that a 'survey with more than 12 questions or takes longer than 5 minutes to complete see a 15% drop in response rate' (Lindemann, 2019) – for this reason twelve (12) questions were set and SurveyMonkey graded it with a three (3) minutes completion time. 565 (five hundred sixty-five) responses were returned, 89% of these were completed in full i.e. responses provided for all 12 (twelve) survey questions. The most often skipped question was Question nine (9), where people were given the option to expand on their preferred mode of information delivery in the future – with forty (40) people skipping this question, a further eleven (11) people responded 'N/A' 'No opinion' or similar, to this question.

The overall goal from the survey was to determine what people's attitudes were to the PIL in its current format – do they use it, how frequently is it used, did the type of medication impact the likelihood of reading the PIL, and how willing were people to moving to reading PILs online.

Survey Results

The survey ran from 11 July 2020 to 13 September 2020. Of the 565 (five hundred sixty-five) respondents 66% were female, 33% were male and 1% preferred not to say.

The age profile of respondents was 10% under 25, 29% ages between 26 and 40, 28% between 41 and 60, 31% between 61 and 80 and 1% over 80 years of age.

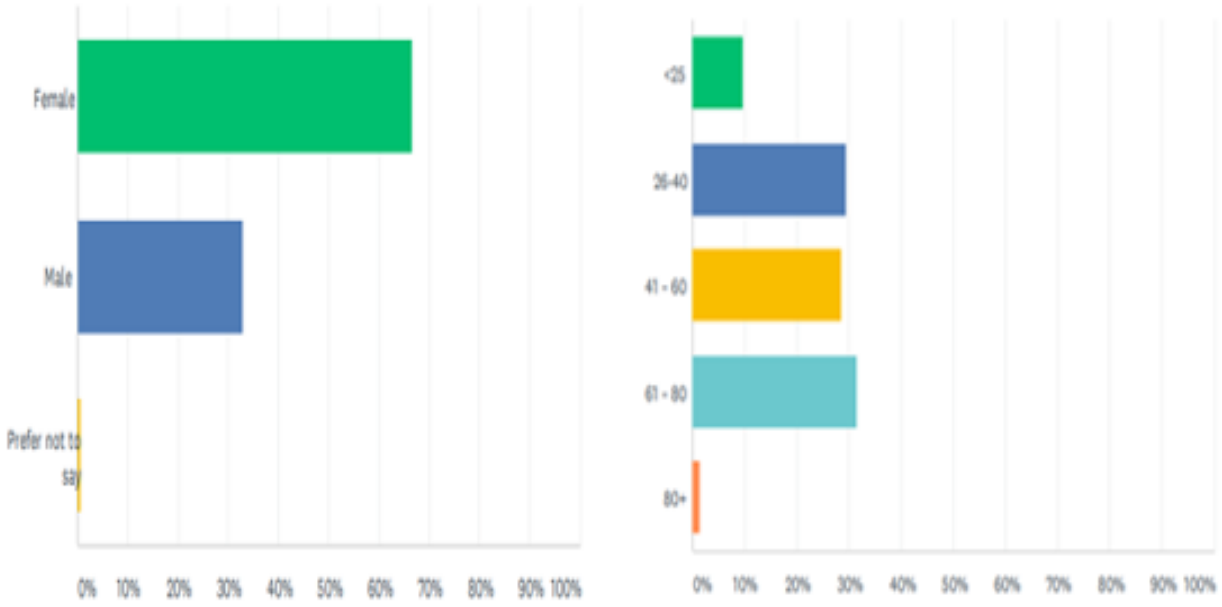

Figure 1: Gender breakdown and age profile of survey volunteers

Two (2) of the survey questions were designed to determine if the likelihood of reading the PIL decreases when medicines are frequently used by someone versus medicines, they use for the first time. With 26% Selecting 'Always' for reading the PIL of a frequently used medication in comparison to 59% selecting 'Always' for reading the PIL for a first time medication, the responses aligned to the common characteristics of a PIL reader in Table 1.

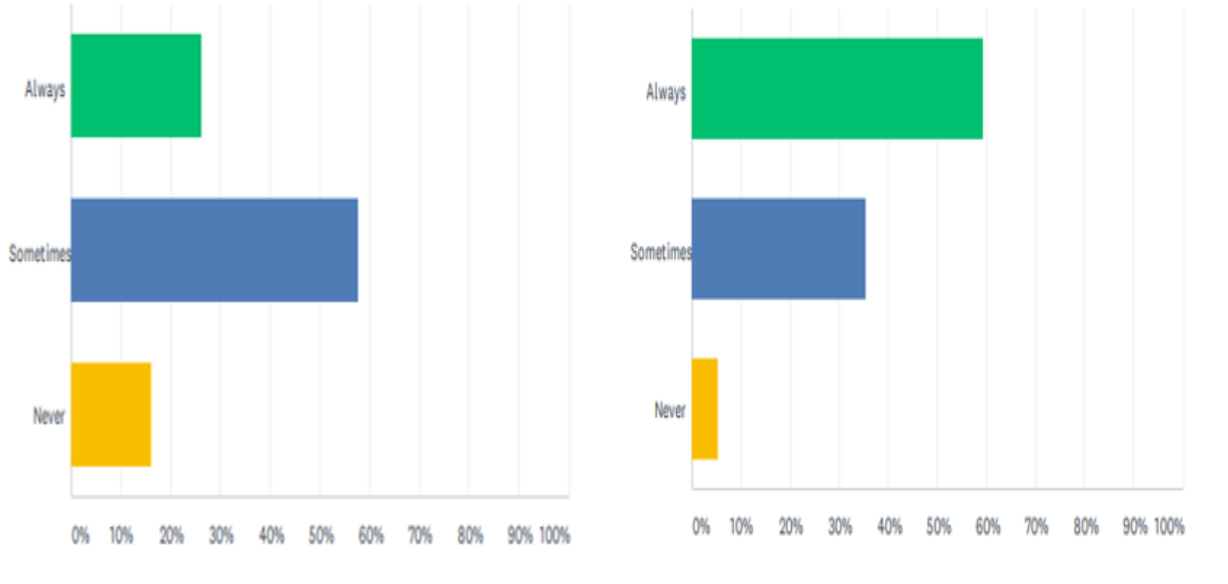

Figure 2: Answers when people were asked if the read the PIL for medicines the frequently use versus medicines they are using for the first time.

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A further two (2) of the survey questions were designed to determine if the medicine type, i.e. prescription versus over the counter, influenced people's decisions to read the PIL. 40% of people selected 'Yes' and 53% of people selected 'No' when it came to reading the PIL for over the counter medicines. These values are the inverse of what was returned for people reading the PIL for prescription medicines with 59% selecting 'Yes' and 35% selecting 'No'. This aligns with the risk that is associated with these medicines i.e. over the counter medicines are considered to be of lower risk than prescription medicines.

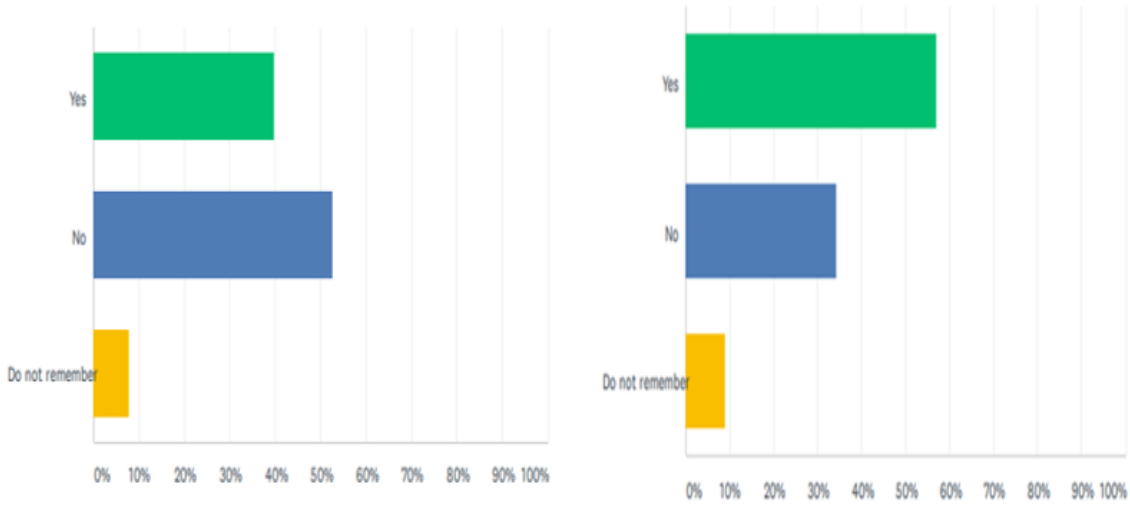

Figure 3: Answers when people were asked if the read the PIL for over the counter medicines versus prescription medicines.

In an attempt to identify the main issues people, have with the PIL they were asked to rank from 'Disagree Completely' to 'Completely Agree' for the usefulness of the PIL, the ease of understanding the PIL and the ability to fold and return it to its box. The results to this question demonstrated that for Usefulness of the PIL and it being easy to read understood – the majority of people selected 'Agree Somewhat', with this option being selected 47% and 41% respectively. For the PIL being easy to fold and return to the box the majority selected 'Disagree Somewhat' with 29% selecting this response.

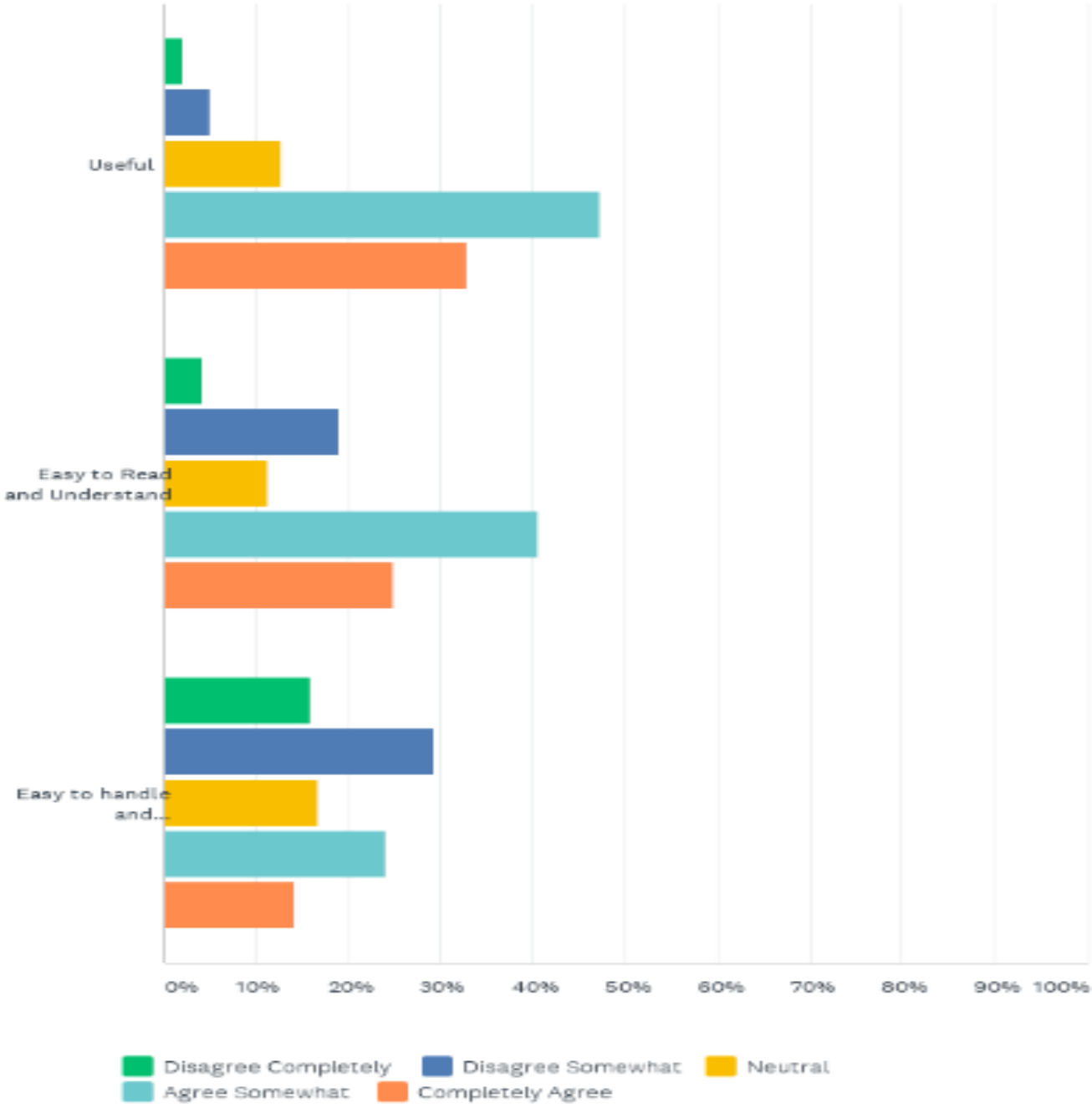

Figure 4: Answers when people were asked to rank if they agreed if the PILS were useful, easy to understand and easy to return to their boxes.

Survey volunteers were asked how they would like to receive the PIL in the future. 45% of respondents selected 'As it is now, paper form', 27% selected 'Electronically', 24% selected 'Printed at Pharmacy' and 4% selected 'Other. In order for the pharmacist to print the PIL, it would need to be online, therefore a move to ePILs would be required to facilitate 51% of

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respondent's preferences. It was noted that people response to this question was directly influence by their age group, with the youngest age group, <25 being the most willing to use an ePIL in comparison to the same age group being the lowest selectors of the current paper version.

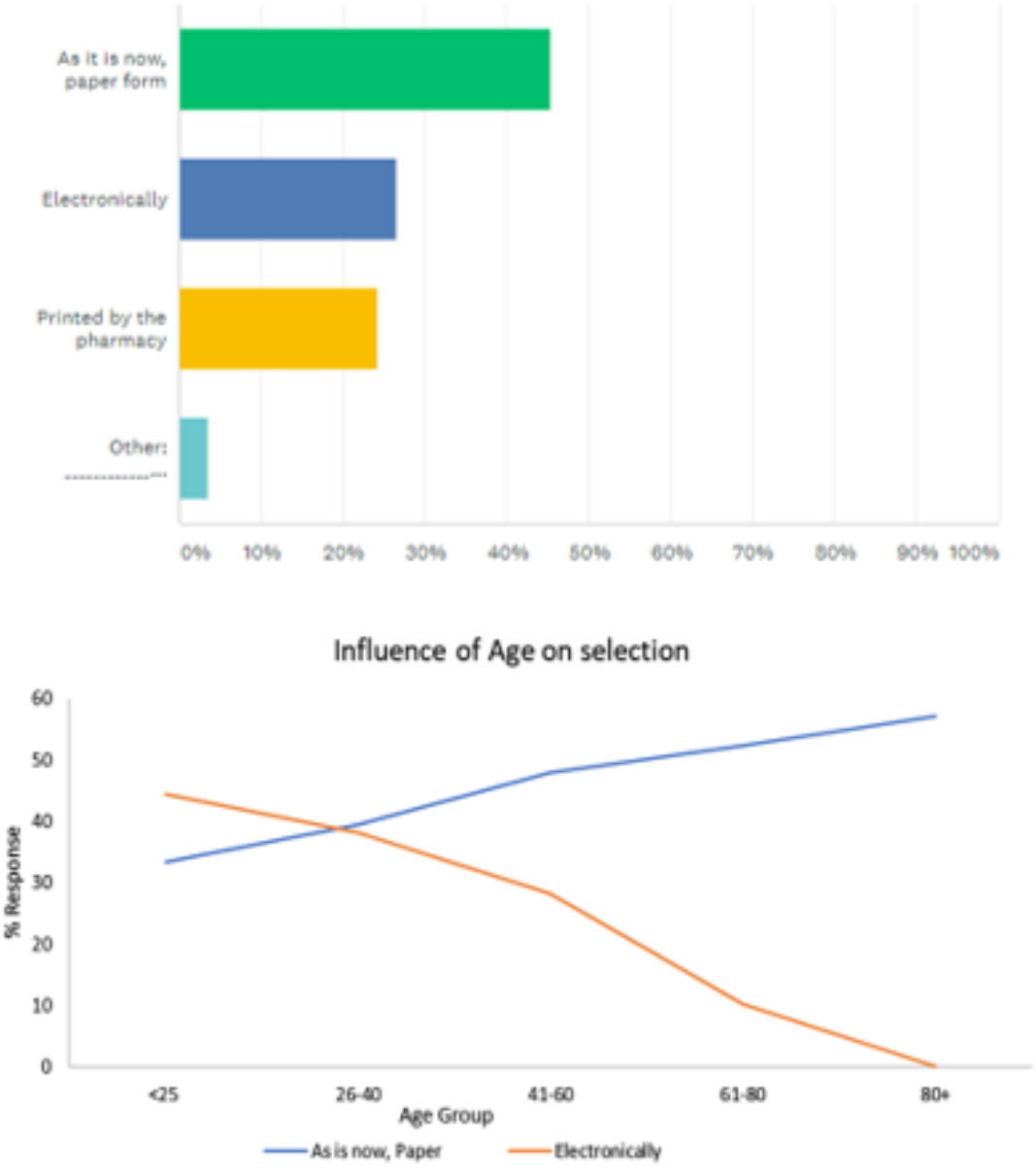

Figure 5: Answers when people were asked to select their preferred method for future PILs and a breakdown of the age category choices for paper and electronic

Question	Please expand on why you selected your chosen answer in the previous question*
Answer Choice	**Example Answers**
As it is now, in paper form	'The paper leaflet is in front of you when you open the medication package, so somehow you are encouraged to read it'. 'Convenience. I do not want to download it and I find it easier to take in information when I read paper copies'. 'I do not have reliable ready-to-hand access to a computer or internet phone at all times' PIL information is critical for my saftey and the saftey of people I give medicine to'. 'More likely to read it'.
Electronically	'An electronic version that is easily searchable would be useful'. 'Could be kept separately to the medicine/no need to try fit back into the package/box'. 'I think that providing the information electronically with a QR code on the product would work well.' 'It's more environmentally friendly'. 'PILs are a waste of paper, you can never refold them, the writing is tiny and often the terms used are jargon'.
Printed by pharmacy	'Tailored patient information leaflet to the patient would be useful'. 'Ease of use presenting only critical information'. 'Current info is very technical – bar is set too high, with the language used. Also the print and technical language is so small, one loses interest quickly'.
Other	'Easier to understand if on the label'. 'Card format – leaflets always crumple'.

*Previous question was: How would you like to receive the information in future

Table 2: Respondents reasons for their selection option for future PIL format

Some respondents also used this open text box to provide their opinions on the PIL in its current format. Table 3 details some of the answers submitted.

Please expand on why you selected your chosen answer in the previous question
Example of answers submitted
'Too long winded with a lot of possibilties on side effects'. 'Too much information'. 'Too much small print for older people or those with impaired eyesight. Critical information should be readable'. 'There's too much information on the leaflet to read it all, I would like the most important info only i.e. dosage, main side effecits, not every side effect that can be mentioned, it's too long and drawn out'. 'Writing is currently too small'. 'Sometimes the information is difficult to understand from the pharma company'.

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Table 3: Example of respondents issues with the PIL

Finally, when asked if an ePIL would increase people's chances of reading the information provided, responses were split 60:40 in favour of 'No'. There was no option to expand on this answer so this result does not allow determination on whether an ePIL would deter the people who are already reading the PIL from continuing to read it if it was in electronic form.

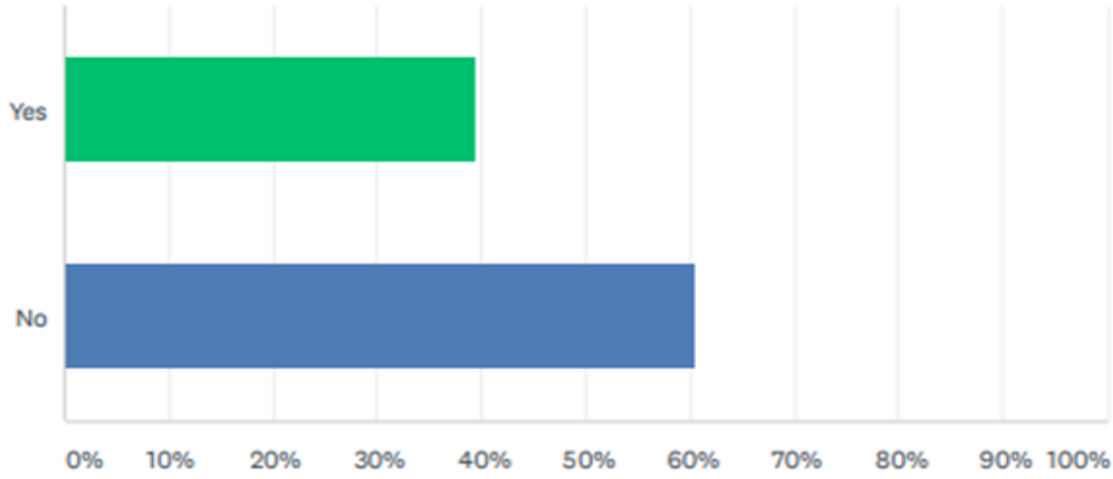

Figure 6: Answers when people were asked if an electronic PIL would increase their chances of reading the patient information provided.

The Case Study

The legislation surrounding PILs in Europe was assessed against the regulations and guidance other jurisdictions and in particular Australia which was the focus of a case study. The PIL, is called Consumer Medicine information (CMI) in Australia. The requirement to have a CMI for a medicinal product is based on the risk classification of the medicine. Australia have a system called Scheduling and medicines are categorized by schedule number, which is risk based, i.e. an OTC medicine is a lower schedule number than a prescription medicine which is considered higher risk. Refer to Figure 7 for an example of the schedule classification, taken from the TGA.

Schedule classification	Type of medicine	Example
Schedule 2	pharmacy only medicine	large packet sizes of paracetamol
Schedule 3	pharmacist only medicine	topical thrush treatments
Schedule 4	prescription only medicine	blood pressure medications
Schedule 8	controlled drug – S8 has additional restrictions on the storage and supply of medicines	strong upload painkillers

Figure 7: Example of medicine scheduling in Australia (TGA, 2012)

In the 1990's, the regulations in Australia were updated so that it was no longer a legal requirement for the CMI to be supplied for Schedule 2 medicines, but it was a requirement for it to be included for Schedule 3 and Schedule 4 medicines. The CMI can be made available online, printed in the pharmacy or sometimes distributed with the carton, however if a PIL is to be provided in this format it becomes part of the labelling and packaging and is subject to other regulatory guidance. To ensure the patient has direct access to the correct PIL, medicine cartons in Australia often include a QR code, which can be scanned by the user.

The legislation on CMIs in Australia have recently changed after much discussion on how to improve the CMI format and address issues that had been flagged with the CMI. Table 4 lists a summary of the main changes introduced.

Change	Details of Change
One-page CMI summary introduced	Ensures more relevant and important information is upfront and easily accessed
Language	Plain English – avoid jargon and medical terminology. Active language. Short sentences. Consistent language and message
Format Changes	New headings and sub-headings. Bold type used for important information that needs to be highlighted to patient. More white space on page. Use of tables. Digitally enhanced.

Table 4: Summary of main change to CMI (TGA, 2020)

The new guidance details digital enhancement that can be utilised. The benefit of the inclusion of the digital enhancements can be explained using subcutaneous injections as an example – links on the CMI could bring the user to a video or tutorial on its use, the TGA consider this a major advantage and shows their willingness to use technology to ensure patients are getting as much up to date information as possible.

Benefits and negatives of PILs

Many studies and articles have indicated that the current format of PILs 'does not meet patient's needs' (Blanck, 2012). The negatives and the positives of both the paper and the electronic formats of the PIL were assessed from the literature review, the interviews, and the survey to determine which of the two formats would be more beneficial to patients. Table 5

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lists the positives and negatives of both PIL formats. The version of ePIL detailed in the EMA-HMA-EC report is the format type assessed given it is the electronic format soon to be introduced

Positives		Negatives	
Paper PIL	**Electronic PIL**	**Paper PIL**	**Electronic PIL**
It is the correct PIL for the medicine that is in the box.	It is up to date and current information.	It is not always the most current version.	It is not accessible to those without internet, smartphone or computer access.
A tangible copy can be retained by the patient or a caregiver.	Is accessible anywhere, anytime on a digital platform.	It is difficult to refold and return to the box.	Unless using a QR code will need to be searched for and user may select incorrect product.
It contains all information in one place.	It is searchable by specific words, headings etc.	The font size is too small.	Adverse impact of poor layout and structure.
It is the 'standard' people are used to.	It is tailored to the individual i.e. font size and language can be selected.	Adverse impact of poor layout and structure.	Technical language and terminology are not user friendly.
Unrestricted access to the information, age, technology capabilities, internet access etc. to not impact access to the paper version.	It can be incorporated into other applications.	Technical language and terminology are not user friendly.	Translation and loss of meaning if user-testing is only performed on one language
	It is environmentally friendly.	Translation and loss of meaning if user-testing is only performed on one language.	
	It reduces material costs for Pharma companies.		

Table 5: Positives and Negatives of both PIL formats

Conclusion

Patients have different requirements, needs and preferences, however the one common requirement of patients is for them to receive current and correct information regarding their medication.

Many of the survey participants stated that they felt the ePIL was a more environmentally friendly option in comparison to the paper format. The survey results demonstrated that the wish to move towards the ePIL versus continuing to use the paper format is very much age dependent. There was an inverse relationship between age and preference for use of an ePIL.

The major positive consequence of the proposed introduction of an ePI (as mandated by EMA-HMA-EC) is 'that increased numbers of people will be able to access it and will wish to access it' (Stewart, 2020), a further advantage according to Dr. Raynor is 'that app developers will be able to incorporate information from package leaflets into their applications' (Stewart, 2020). By it being online it ensures that the most current version of the PIL is available to patients – however given that it is unclear if patients are even aware that they may not be getting the most current version of a PIL with their medicines, it has yet to be determined if they will realized this as a benefit. It is recommended that an education programme for patients be introduced on this area.

Benefits of the ePIL that may be acknowledged by patients more readily will be the ability to search for keywords, the option to make the font size bigger and being able to check the PIL without having to physically bring it with them when they leave home.

With the introduction of the ePIL, the risks posed by the communication gap as a result of Irish pharmacies dispensing medicines to patients without providing the PIL, will be potentially mitigated in that patients can access it themselves online. It does not however aid the people with low levels of digital literacy for which the paper PIL has been identified by EMA, HMA and EC as being crucial. Further critical assessment on the follow through of the distribution of the PIL to patients after it leaves the manufacturing site is much needed.

In short, the ePIL will give patients access to more clear, accurate and current information than they are currently being provided using the paper PIL – it can definitely be considered a step in the right direction. Some of the ePIL disadvantages including inaccessibility by people without the correct technology are more difficult to rectify than negatives which exist for both formats such as the language, the layout and the technical language. By not addressing these issues in conjunction with the introduction of the ePI, there is a disservice being done to the patients of Europe.

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