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AESGP, EFPIA and Medicines for Europe Survey on availability of digital information for medicinal products in Europe

The pharmaceutical industry fully supports the provision of comprehensive, accurate and up-to-date regulator-approved information on medicinal products, both for patients and healthcare professionals (HCPs). Such information must be easily accessible, allowing the patients/HCPs to obtain, identify and use the information necessary to meet their individual needs. Patients' role in their own health care is changing from patient compliance to patient engagement. Therefore, the importance of the product information is increasing, and content, readability and layout are considered key pillars for its correct and appropriate use.

In addition, there is a need to explore alternative innovative pathways of disseminating information in electronic format. The use of existing and evolving technologies could allow immediate access to the most recently regulator-approved 'real-time' product information, rather than relying on potentially out of date paper copies or electronic information from non-trusted sources. This approach would enable patients to search trusted information sources in a tailored fashion to meet their own needs. The information for patients and HCPs could be made available electronically in a way that allows quick and easy access to the preferred level of information and in a user-friendly format.

Digital information about medicinal products

One of the three focus areas of the European Commission's priority for 'Digital Single Market' is promoting better on-line access to goods and services across Europe. The AESGP, EFPIA and Medicines for Europe (IATF eProdInfo) member survey provides information on the digital availability of Product Information (PI) and the projects that are on-going to further enhance digital information services.

National competent authorities / Ministries

In accordance with European legislation[1] publication of approved product information (SmPC and PL) is expected by the national competent authorities (NCAs). According to a survey by the IATF eProdInfo[2] access to approved PI (Summary of Product Characteristics (SmPC) and Patient Leaflet (PL)) is provided by most of the NCAs for nationally and decentralised authorized medicinal products (NAPs) on their webpage while they provide a link to the European Medicines Agency (EMA) for product information of centrally authorized medicinal products (CAPs). For some authorities it is indicated that publication of updated product information can have a delay of up to several months e.g. due to internal administrative procedures such as publication of product information only after issuing a national approval letter.

The Inter Association Taskforce (IATF) survey showed only a few NCAs use modern technologies e.g. xml is indicated. For most of the NCAs publication of PLs is indicated to be either pdf or Word which makes accessing these information portals less attractive compared to services who provide more user friendly access routes and provide additional, patient-relevant information either as video or an audible form.

[1] According to article 57.1.b of regulation 726/2004/EC or article 21.3 of directive 2001/83/EC

[2] IATF eProdInfo member survey 2017

Search capabilities are very often limited and mostly allow for identifying a medicinal product and its respective SmPC/PL. The functionality rarely provides search capabilities and easy access, to patient relevant information such as undesirable effects and posology.

Other providers

The internet is full of webpages providing easy access to medicinal information and very often the source has to be considered non reliable. These webpages are very often not aware of the latest update i.e. new safety information and/or recommendations by the Pharmacovigilance Risk Assessment Committee (PRAC). But in some countries third party providers have started to fill the gap and provide SmPCs and PLs as well as specific services addressing patient and carers needs. Some of these providers (such as eMC (UK), FASS.se (SE), Rote Liste (DE), etc) have offered easy access to approved medicinal product information in a reliable manner for years and their work is acknowledged by the NCAs. A concerted effort across EU is needed to promote regulator-approved SmPCs and PLs.
Two major pathways are meanwhile established a) harvesting information directly from NCA webpages and b) direct delivery and release of updated product information via pharmaceutical companies themselves. The services provided incorporate easy access to approved product information via webpage and in some cases even mobile apps in a simple to navigate and consumer friendly design. We are also seeing pharmaceutical companies engaging in supportive media such as videos and drawings as additional enhancements. Likewise, making use of 2D codes such as QR codes becomes more and more common for these services. One downside can clearly be seen in the limited range of medicinal product coverage. Secondly, Industry has to pay for the services and therefore, not all medicinal products information is potentially available to all patients.

General use of Internet

According to Eurostat[3] (survey Dec 2016) 85% of European households had access to the internet from home in 2016. This share has gradually increased since 2007 when only 55% of households had access to the internet. Access to either fixed and/or mobile broadband connection increased to 83% of the households. In EU on average 79% of individuals make use of the internet at least once a week and 71% of all individuals use it every day or almost every day.

A study[4] was carried out for the European Commission by IHS Markit and Point Topic covering 31 countries and analyses the availability of nine broadband technologies and collected data shows 218 million EU households (99.9%) had access to at least one of the main fixed or mobile broadband access technologies at the end of June 2016 (excluding satellite). Rural broadband coverage remains lower than national coverage across EU member states at 92.6% of rural EU households.

Internet activity by age group

86% of European internet users on average aged 16-74 have sent and received emails for private purposes and 80% have searched for information.

Eurostat details that “age and level of formal education have a significant impact on the use of the internet by the individuals. 96 % of individuals aged 16-24 were regular internet users against 57 % in the 55-74 age group. Individuals with a higher level of education were almost all regular internet users (96 %), while less than 60 % of individuals with a lower level of education used the internet regularly.” The proportion of individuals who have never used the internet has reduced significantly from 37% in 2007 to 20% in 2013 and at the time of this report, it was 14% in 2016.

[3] http://ec.europa.eu/eurostat/statistics-explained/index.php/Internet_access_and_use_statistics_-_households_and_individuals

[4] Broadband Coverage in Europe 2016, Mapping progress towards the coverage objectives of the Digital Agenda, Executive Summary

Finding information about goods and services are the most popular activities. Online services on health related information are more used by individuals aged 25-54 and 55-74 compared to the younger age group (16-24).

IN CONCLUSION

To address the needs of patients with regard to reliable and trusted information on medicinal products in an easily accessible form while supporting their current life style, IATF is looking to work with the European Commission, EMA and patient groups to provide a pan-European solution that builds on easy access routes based on existing technologies and established pathways of electronic information dissemination.

The Association of the European Self-Medication Industry (AESGP) is the official representation of manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe.

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Examples of country specific projects to further develop digital information services

Austria

SpeechCode, a project developed by the Sigmund Freud University in cooperation with various associations, provides product information in an audible version and a safety feature which allows direct reporting of adverse events.

Belgium & Luxembourg

A pilot to test electronic dissemination of product information to patients is ongoing in Belgian hospitals while the medicinal products no longer contain a patient leaflet in paper form.

Germany

The pilot project "Gebrauchsinformation 4.0" aims for leveraging an infrastructure that would allow patients to rely on electronic dissemination of PLs only, either via webpage or on a smart device by scanning a unique code. For all those patients with no access to internet or limited capabilities in using the internet direct provision of most recent PL is ensured by printing the PL in a pharmacy upon request.

Italy

This project initially commissioned by AIFA has now become a routine and successful database used widely by pharmacies throughout Italy. By establishing a database that provides pharmacies with access to the most recent PLs and capabilities to print the newest information for patients, the system has helped reduce the number of immediate product recalls due to packs containing 'out of date' product information. The latest regulatory-approved PI is provided with an old pack during the transitional period of 6 months required to leveraging existing stock and immediate cost savings has been achieved.

Spain

AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) has an application for mobile devices to provide PI for all the medicines authorized in Spain to healthcare professionals and general public. It can be downloaded for free and it is available for the most common mobile devices iPhone, iPad and Android. People can read bar codes with their iphone/Android to access PI. This application is based on data in the register of medicines authorized by AEMPS which is intended to finally cover nationally and centralised authorised medicinal products. Through this application the latest authorized SPC and PIL in pdf format is accessed.

The Netherlands

Small movies are made available to explain in 5 minutes key information of a medicinal product as listed in the PL. The patient can access the content via unique access codes handed over with the medicines in the pharmacy.

United Kingdom

Since November 2015, BGMA (British Generic Medicines Association) has coordinated 7 patient information work sharing projects, working closely with MHRA. Each has involved the production of one high quality set of materials that have been distributed to patients through their healthcare professionals (couple of examples: Voriconazole – healthcare professional Q&A brochure, healthcare professional checklist, patient alert card and Abacavir (ALL ELECTRONIC) – patient alert card, healthcare professional risk minimisation brochure. Between 7 and 12 different generic companies

have taken part in the projects, in one case joined by the originator. Initially the sole route of communication was physical mailing. With experience a more plural approach has been developed, tailored to the messages to be delivered and the patient population for the particular medicine. This has led to the increasing use of e-communication, with the first 'all electronic' delivery being completed in mid-2017, for reinforcement of well-known safety information. The electronic routes used have been the electronic Medicines Compendium and the participating company websites, supported by the established company medical information services.

E-Labelling Country Summaries – 2017 Update

Country	Electronic Availability of PILs?	Trade Association position on E-Lab.	Regulatory Agency position on E-Lab.	Current initiatives	Internet usage (source: Eurostat) to be updated
Australia/NZ	PILs provided at point of dispense (pharmacists prints) for most products, unless otherwise desired by sponsors. Exceptions are for parenteral products, which must have a hardcopy PI (physicians prescribing info). Distribution of PILs electronically (and upload of PIL (CMI in Aus)) and PI is undertaken by a 3rd party provider.	Accepted other than for injectables. Currently part of a small group working with TGA to examine need for printed leaflets in parenteral medicine packs.	See previous.	No further initiatives.	
Austria	The agency provides an online database where all current approved PILs/SmPCs for specific products can be found & downloaded. It also provides the possibility to search for products registered in Liechtenstein. In case CP the agency refers to the EMA homepage.		The Austrian Agency for Health and Food Safety has approved the project, and is supportive of the programme. External attorneys are trying to broaden participation of the project to other countries.	SpeechCode' has been developed by the Sigmund Freud University in cooperation with various associations in 2012. It's an audible PIL and product information. In 2013 the 'Call4Safety' feature was added - where consumers can directly report AE out of Speech Code PILs. There is a strong movement of PIL adaptation, under the scietific programme "Patient Information and Consumer	81 % of households have internet access 63 % of individuals use it on a daily basis

				Protection"; which brings different stakeholders together.	
Belgium	The Federal Agency for Medicines and Health Products (FAMHP) publishes SmPCs and PILs on their website, publicly accessible. http://bijsluiters.fagg-afmps.be/?localeValue=fr Yet, these versions are not always up to date, the FAMHP does not upload the new versions at the time a variation is approved, but only at the administrative closure when an updated MA is issued (can be months/years later). The FAMHP is working to have PILs and SmPCs available in xml files in the coming months. The Trade Association (pharma.be) has flagged this on request of the MAHS, but the FAMHP remains adamant. The Trade Association pharma.be has its own website where all SmPCs and PILs **of pharma.be members** are published and publicly available. http://www.e-compendium.be/ Continuous update occurs by the MAHs; user friendly documents allowing tailored search of information, access via mobile	pharma.be is closely working with the Belgian Competent Authorities (and the EU Authorities) to have national pilot projects set-up by the authorities to test e-labelling in hospitals in Belgium FEBELGEN POSITION: FeBelGen supports the use of the e-leaflet because of its advantages compared to current situation where 3 official languages influence readability on in-pack leaflets. Moreover the use of the e-leaflet would contribute to a more cost-effective healthcare system and have a positive effect on the use of natural resources (avoid print & paper use). However the authentic source of the information should be the NCA. If investments should be done to allow ad-on applications, they	FAMHP does not believe e-inserts can replace paper insert in the package as from today since not every individual has internet access. However, they are supportive to explore the use of new electronic technologies to disseminate the information on medicines via pilot projects for instance. The Famhp is open and supportive to set-up pilot projects to test e-labelling starting in "protected environment" such as hospital for prescription hospital used medicines. The Minister stated in the Pact for the Future for the patient, that the publication of the leaflets at the FAMHP needs to be optimised by means of user friendly apps. FAMHP does not believe e-inserts can fully replace	Proposal to have a pilot project to test e-labelling (**without any paper inserted information in the packaging**) in hospital used only medicines, supported by the FAMHP. Hence the minister of health in Belgium (together with the minister of health in Luxembourg) has aksed to the EU commission the necessary derogation to conduct this pilot in their territories for a defined period of time. Derogation has been granted by the EU Commission in Dec 2017. The pilot project can therefore now be launched. Authentic source at FAMHP: leaflets will be included in the source database SAM2 that will equally be used by other institutions (eg NIHDI) as such allowing access to the documents in their electronic formats (now: PDF) Several applications (B2B, B2C) are being developed to allow extracting (partial) information from the leaflet and presenting it in a customised manner but these are not based on the authentic source (FAMHP database) and require extra resources on MAH	**85 %** of the belgian households have internet, mostly broadband (**97 %**). **11,2 %** of individuals (16-74 yo) never used internet **36,9 %** of individuals (16-74 yo) use cloudstorage or online computing services **69,3** of individuals (16-74 use social media

		should be done on NAC level.	paper insert in the package – not every individual has internet access. The pharmacy-printout PIL at medicine delivery requires appropriate systems – discussion with the Pharmacist Association has to occur, to also address budgeting constraints.	level in order to be able to participate in these initiatives. It is FeBelGen's position that the authentic source of the information should always be the NCA. If investments should be done to allow ad-on applications, they should be done on NCA level and so industry can avoid duplication of resources needed	
Bulgaria	Latest approved documents (SPCs, PILs, etc.) may be found in NCA website, managed by HA specialists No trade association website with ePIL available. Local labels do not have links to company or industry websites.	Position unconfirmed.	No official position.	Bulgarian Drug Agency (NCA) is planning to upgrade is website in 2016. It is expected the access to PILs to be greatly improved.	54.6% of pop. use internet daily, 59.1% of households have internet access.
Canada	The approved patient information section of the Canadian Product Monograph (label) includes the website for Canadian companies but not a direct link to the product information. Health Canada also posts product monographs (for branded and generic medicines) onto their website – not user friendly and intention there to create more accessible site.	No formal position expressed – but Canadian trade associations very supportive of transparency for the customer.	Revised product monograph guidance recently issued by Health Canada, stating expectation for manufacturer to supply the consumer information document to the pharmacist or doctor for patient/consumer distribution. Reference	Not directly associated with E-Labelling : New regulations came into force on June 13th, 2015 imposing new obligations on health products sponsors to: • Provide information in plain language; • Assess the name of their health products to avoid confusion; • Submit mock-ups of labels and packages for review; • Indicate how to report harms on their product's label; and	83% of households have internet access, 75% in rural areas Average Canadian spends 45.3 hrs a month on internet sites.

	The PIL is also available via eCPS (electronic Compendium of Pharmaceuticals and Specialties). eCPS is the Canadian Drug Reference for HCPs which is edited and managed by the Canadian Pharmacists Association. Patients do not have access to eCPS however, if a HCP has registered with eCPS the HCP has access and can obtain a "printable format" of the PIL.		to a website/ telephone # on a product package is insufficient.	• Provide information in an easy-to-read format As part of these new regulations Health Canada recently released a revised Part III: Patient Medication Information section of the Product Monograh; simplifying information.	
Croatia					
Czech Republic	The Czech competent agency (SUKL) provides an online database of authorized products in its website (www.sukl.cz), containing current approved PILs/SmPCs for nationally, MRP/DCP products as well as for CP products. The CP products information is provided as link to EMA web page. The website is publically available. Responsibility to update lies with the agency.	No official position.	No official position.	No further initiatives.	73% of pop. use internet daily, 54 % of households have internet access.
Denmark	All PILs (irrespective of approval procedure) must be uploaded at an Agency homepage by the MAH within 3 months after SmPC change approval (variation). Fixed format			Danish Trade association: E-labelling/PILs will be a 2014 focus area. There are also other prescribing texts available, published by Dansk Laegemiddel	An App for iPhone/Android has been developed by the DHMA in 2012,

	requirements exist for the uploaded PIL (Jan 2014).			Information A/S (DLI). The catalog which has been printed since 1976 has now been replaced by the electronic version - available since 2003. It contains information about medical products and disease areas written by KOLs - yet it is not always in compliance with approved SmPC (a disclaimer is provided, responsibility lies with DLI). It is widely used by prescribing physicians. Danish PILs are now also available at: http://www.indlaegssedler.dk/ The text is taken from the Agency home page and updated every 2 weeks (approx. 200 PILs are updated during a 2 week period). The DMA has consented to this approach which makes it much more easy for patients to make free text searches. It is possible for companies to add small videos or drawings of non-promotional nature e.g. user instructions. Combined with an app a scan of the QR Code can take the patient directly to indlaegssedler.dk	but awareness and use of App is low. It does not replace physical PILs in packs, and is used by scanning the EAN13 bar code on secondary packaging material. 93 % of households have internet access, 84 % of individuals use it on a daily basis

				The DMA are considering to make a link directly to DMA adverse event reporting site. The text is in all PILs but it could be useful to make it a link.	
Estonia	Latest approved documents (SPCs, PILs, etc.) may be found in NCA website, managed by HA specialists	Positive>negative: NCA position received at the end of May 2014 on 2D coding acceptance for ePILs presentation on folding cartons. 2D codes can be used to direct to NCA official website for downloading latest approved PILs.	The Estonian Agency is following CMD(h) guidance document on QR/2D codes. The following can be provided via QR code (positive list): package information leaflet, additional risk minimisation materials (for patients) which have been approved by the NCAs (i.e Educational material as outlined in the Risk Management Plan), code can be printed for counter medicines and prescription drugs. The inclusion of the QR code cannot replace the printed package leaflet, the code has to refer on the NCA website published information. QR codes can be put on an outer carton and/or PIL, in case of small packages codes can be put to	The topic is ongoing at local trade association regulatory working group.	79% of pop. use internet daily, 80% of households have internet access.

			inner surface area, in case of multilingual packages 1 code can be used (on a first displayed page links to specific languages are shown). Codes should not influence readability. Following sentence shoudl be added to PIL: Detailed and updated information on this product is available by scanning the QR Code included in the <PIL> <outer carton> with a smartphone. The same information is also available on the following URL: [URL to be included] <and the <NCA> website >>		
Finland	The Pharmaceutical Information Centre Ltd has a website with all PILs ("laakeinfo.fi") in both Finnish and Swedish. The site also contains audible PILs in Finnish (but not Swedish). The Pharmaceuctical Information Centre is a drug information and skills development company owned by the	No official position but eLabelling viewed positively.	Fimea does not have an official position but has stated that unless changes are made to EU legislation, ePILs could not be the sole format.		92 % of households have internet access 85 % of individuals use it on a daily basis

	trade organisation Pharma Industry Finland (PIF).				
France	A PILs and SmPC database exists on all registered products, owned by the Ministry of Health and fulfilled by ANSM, HTA body and national social security insurance. A new service of this database has been released : it uses the flashcode on the box of the drug and give access to product . For CP products a link to the EMA website is provided.	None to date, LEEM did not partake in the WG at EFPIA.	ANSM is still working on IT tools but mainly for notification purpose. We are not aware of ANSM position on e-labelling but the legal way to provide the PIL to the patient is via the pack.	None	61% of population have been in contact with official governments via internet 80% of population use internet daily 70% of population have a high home speed internet connection.
Germany	PILs are available from the internet from different services: a) DIMDI b) Rote Liste Service GmbH c) Company Websites Comments: a) service in co-operation with the authorities; should cover PILs for all products approved in DE; not very popular, quite demanding search engine and not user-friendly b) voluntary use by companies, initially created to fulfill the requirements for people with impaired vision; companies have to pay to get their PILs published	Current view is that E-labelling as single path to provide the PIL requires a change in legislation. Until then companies are encouraged to offer it as an add on. Close collaboration with EFPIA to foster the opportunity to provide the PIL via electronic means in the first place rather than with the pack. This includes an option for patients	The only legal way to provide the PIL is through the pack. Other pathways are acceptable as long as they are not connected to any promotional activity.	The German pilot builds an integrated digital system, providing up-to-date authorized information about medicines to patients in a user friendly and easily accessible digital format with print option (in close collaboration with the European initiative). The pilot involves the associations BPI and vfa, the Rote Liste Service GmbH and 18 pharmaceutical companies together with representatives from regulatory authorities, pharmacists and patient organisations. Current planning is to leverage in a next development step on the infrastructure build for serialisation	82% of all households have access to the internet 80% use the internet on a daily basis, peak at 16-24 yrs :95%, though at > 65 yrs: 62% 76% of women and 83% of the men use the

	c) Increasing trend for companies to publish their PILs on their websites.	without access to the internet to get a print-out at the pharmacy.		requirements according to directive 2011/62 to allow batch specific information. The 'AG Beipackzettel' (working group on Patient Information Leaflet), founded around 2009 focusses on readability and testing of PILs.	internet on a day to day basis
Greece	Our Health Agency (EOF) provides an online database where approved PILs/SmPCs can be found & downloaded. Unfortunately, the database is outdated an due to inadequate maintenance we cannot fully trust its contents.	We are not aware at the moment of a local Trade Association position on the e-lab. However, one of the Trade Associations maintains a SmPC, PIL database via the kind contribution of the latest approved texts by its members	We are not aware at the moment of a Greek Regulatory Agency position on the e-lab.	No initiatives.	49% of the population are frequent users (i.e. daily users of the internet)
Hungary	Current approved documents (SPCs, PILs, etc.) can be found only on the NCA website, and no link to industry/company website where electronic version of the label/PILs would be placed	No official position is available.	Unaware of it.	Unaware of further initiatives.	75 % of households have internet access 68 % of individuals use it on a daily basis

Ireland	The IPHA hosts a website providing electronic SmPCs and PILs to the public and HCPs; only available to member companies, each has full responsibility to ensure the currently approved document appears on this site at all times. Advantage: instant ready access to information on all medicines from IPHA member companies. Disadvantage: includes all innovator companies, but excludes most generic companies (not IPHA members). End users are Industry, HCPs and patients.	Little progress has been made from IPHA (Irish Pharmaceutical Healthcare Association) other than circulating the link to the NIVEL survey from companies to respond directly. Industry (MAHs) looking to add this to the regulatory IPHA agenda	Topic was discussed at the EU Annual TOPRA symposium in 2012, co-sponsored by the HPRA . The HPRA are reserved of the e-labelling, using cautious approach after learning that the User Testing exercise had not resolved issues of readability of the PIL. Their view is to await output from the EC review and at an HPRA/IPHA meeting denied further comment until then. This aligns with their general approach where they look to follow EU lead.	The Health Products Regulatory Authority (HPRA) publish SmPCs and PILS on their website, managed by HPRAyet companies carry out a quality check on the documents due to be issued following approval of a variation/remewal/new application. SmPC's have a longstanding electronic publication history, with PILs added more recently. HPRA upload within 14 days. The HPRA provide a link to the EMA website, the EPAR for SmPCs/PILs of CPs. This covers all MAs - innovator and generic. IPHA has approached Industry to provide research topics for an MSc student; e-labelling has been suggested as a topic, along with background and rationale.	82 % of households have internet access 61 % of individuals use it on a daily basis
Italy	On AIFA's website a database with SmPCs and PILs of all approved products, including CP products is available, with a list of those products which had a labeling update in the last 4 months. Also, according to AIFA's Provision coming into effect on June 2014, after a labeling update, companies will no longer need to recall "old" batches, as the pharmacists will have to print out	Farmindustria and other pharma associations (Assogenerici, Assosalute) have stipulated a general agreement with Farmadati for the central data base collecting all new leaflets and making them available ot the pharmacists (see left)	according to the law DDL n. S. 2085 - 17th Annual Law for the Market and Competition (PIL) the pharmacist has been given the possibility to provide the updated PIL in digital format, too as per below text:		69 % of pop. use internet daily, 54 % of households have internet access.

	from a central database the updated leaflets to be handed over to the patients with the "old" packs. The pharmacists will also see a summary of the changes occured, so that they can furnish details to the patients of what has been changed. The central database has to be paid by the companies. (see next column for further details)	The plants will have to implement the new labels within 6 months from the change, having so enough time to buy the new packaging components => no risk of stock out situations.	DDL n. S. 2085 - 17th Annual Law for the Market and Competition (PIL). *In the case of changes made to the package leaflet - the patient chooses the procedure for the withdrawal of the replacement leaflet, conforming to that authorized in paper or analogical format or through the use of alternative digital methods and without charges for public finance article 1, paragraph 164.*		
Latvia	All current approved labelling documents (SPCs, PILs, Labelling) for medicinal products registered in Latvia can be found in the NCA website (www.zva.gov.lv) and this is managed by the HA specialists. In case of centrally registered products, the agency refers to the EMA homepage.	No official position.	No official agency position on e-labelling is available.	While no official agency position is available, NCA advise to refer to CMD Position paper on the use of the Quick Response (QR) codes to provide information about the medicinal product (April 2014) recently published. Currently no further initiatives.	72 % of households have internet access, 60 % of individuals use it on a daily basis
Lithuania	The agency provides an online database where all current approved PILs/SmPCs for specific products can be found & downloaded. In case of centrally registered	No official position.	No official position.	No further initiatives.	53 % of pop. use internet daily,

	products, the agency refers to the EMA homepage.				65 % of households have internet access.
Luxemburg	SEE Belgium_ France database and Agency website	In collaboration with Belgium, APL is closely working with the Luxembourgian Competent Authorities (and the EU Authorities) to have national pilot projects set-up by the authorities to test e-labelling in hospitals in Luxembourg	LUX agency does not believe e-inserts can replace paper insert in the package as from today since not every individual has internet access. However, they are supportive to explore the use of new electronic technologies to disseminate the information on medicines for instance and to set-up pilot projects in collaboration with Belgium to test e-labelling starting in "protected environment" such as hospital for prescription hospital used medicines.	SEE BELGIUM	See Eurostat
Netherlands	The MEB (National CA) provides approved PILs and SmPCs for nationally and MRP DCP products and links to the approved Annex for CP products on their website. Responsibility to update lies with the MEB and the website is publically available for all.	Nefarma (EPFIA) and HollandBio (EuropaBIO) have not published a specific position. In principle, trade associations support good access of current	The MEB does not have an official position on E-Labelling published.	The KNMP (Dutch pharmacists association) makes (the most important) information on drug products available via their databases and they search the MEB website and other documentation for updates to product information to include in	97% of the Dutch population has access to the internet (CBS statline April 2014)

	The database provides elaborate search functionalities.	texts to relevant parties and e-labeling might help.		the G-standard, which populates the pharmacists databases with product information. The Health Care Institute of the Netherlands (Zorginstituut Nederland [ZIN]), the Medicines Evaluation Board (MEB), Pharmacovigilance Centre Lareb, the Medicinal Products Bulletin (Geneesmiddelenbulletin [Gebu]) and the Institute for Responsible Use of Medicinal products (Instituut voor Verantwoord Medicijngebruik [IVM]) have signed a declaration of intent to provide more up-to-date and clear information about medicinal products. The ultimate aim is to promote the appropriate use of medicinal products. This corresponds to one of the aims in the MEB Strategic Business Plan 2014 - 2018. The MEB and the Netherlands Pharmacovigilance Centre Lareb currently already share information with the (digital) Pharmacotherapeutic Compass (FK), which will form the backbone of the information provided to prescribers. The focus is now on streamlining the information to healthcare providers and this will indirectly benefit the patient. Subsequently,	88 % of individuals use it on a daily basis (CBS Statline April 2014)

				the information to patients will also need to be improved. See also http://english.cbg-meb.nl/latest/news/2015/06/01/improved-information-for-healthcare-providers-about-medicines	
Norway	Felleskatalogen, a daughter company of the Norwegian trade association publish PILs on their website. The Norwegian Medicines Agency links to this website and the website is a commonly recognised source for information for medicinal products in Norway. All companies, including generics and parallel traders upload their PILs to this website. Felleskatalogen has launced two apps; one for patiens, and one for healthcare professionals. By scanning the EAN code on the medicinal pack, patients are routed to the PIL, and healthcare professionals are routed to the abbreviated SPC. Alternatively, if you do not have any of the apps installed, some products has a QR code printed on the pack, directing you to the PIL's website. Norway's ePILs are provided in an XML-format, not as pdf. The user can easily select the chapter of interest and increase the font size if needed, which makes the information easily accessible.	The trade association's strategic program is to be a driving force regarding implementation of electronic PILs. The trade association are having meetings with NoMA to further discuss the ePIL framework according the the white paper from the parliament.	A white paper from the parliament was published in 2016 is positive to the implementation of ePILs instead of or in addition to paper PILs.	The trade association is working closesly with the Norwegian medicines agency to ensure an automatic delivery of updated PILs to Felleskatalogen for products in the MRP/DCP and national procedures, upon approval of new version of the PIL by the agency. The PILs will be delivered in PDF format and Felleskatalogen will convert the information to XML before it is published to the website and apps. This process will ensure that all ePILs are updated in a timely manner. In 2018, Felleskatalogen will start the development of a solution to gain updated PILs from the EMA website for products approved in the Centralised Procedure. The Norwegian trade association is planning a pilot project to replace the paper PIL with e-PIL only for some products.	98% of households have internet Access (Eurostat 2015)

	Some products also have instruction videos to show how to use the product, e.g. how to prepare the product, how to inject or how to inhale. These videos are available on the website and in the apps.				
Poland	The Polish Agency provides approved PILs and SmPCs for nationally and MRP, DCP products on their website. For CP products a link to the EMA website is provided.	No official position.	The Polish Agency provides approved PILs and SmPCs for nationally and MRP, DCP products on their website. For CP products a link to the EMA website is provided.	No current initiatives.	75% of households have internet access 60% of individuals use it on a daily basis 77% of population have PC at home
Portugal	Latest approved SmPC and PILs found in NCA website, centralised products referred to EMA website. "SAVE in RECIPE" (eMed.pt) for smartphones (iOS & Android): access price of medicines & PIL. Alerts, Pharmacy location, etc included There are also some initiatives promoted by the MAHs making the PILs available on its webpages. These are projects under the responsibility of the MAHs, developed on an individual basis.	APIFARMA No official position for now.	No official position, yet app available with PIL online. So far not intended to replace paper versions.	No further initiatives. Results from a study on digital literacy in health launched in May 2017, involving 3,500 National Health Service users in Portugal, show that 88% of respondents say that they use the internet frequently to seek information about health, but only 20% consider it credible. Data from the study reveal that "credibility and excessive amount of information were the main problems pointed out by 78% and 38% of participants, respectively. There is a huge diversity of health information sources on the Internet, but there is no	63% of pop. use internet daily, 48% of households have internet access. (see also column "current initiatives")

				certification methodology for these sources. " The study also revealed that half of the participants believe that the information transmitted by doctors is not always perceptible and enlightening. 60% of respondents admit to use the internet to look up for disease symptoms and their meaning; searching on available treatments (47%), information on doctors and hospitals (43%) and disease prevention (41%). Note: The study was conducted by the Health Information Technologies Commission of Health Parliament Portugal (not published /available). Source: Press Release (link)	
Romania	Latest approved documents (SPCs, PILs) may be found on the NCA (National Medical Devices) website. For Centrally Approved Products the current PILs and SmPCs in Romanian language are posted on the EU Community Register of Medicinal Products.	No official position.	No official position.	No further initiatives.	43% of population use internet regularly
Slovakia	The agency provides an online database on its website, containing all current approved PILs/SmPCs for specific products. In case of centrally registered products, the agency refers to the EMA homepage.	Slovak Association of Regulatory Affairs Professionals (SARAP) regularly challenges the agency. No official position of the agency.	No official position.	No further initiatives.	78 % of households have internet access

	http://www.sukl.sk/en/servis/search/searching-on-the-database-of-medicinal-products?page_id=410				61 % of individuals use it on a daily basis
Slovenia	Slovenian agency maintains an online database where all current approved PILs/SmPCs for products registered in Slovenia can be accessed. CP products are referred i to the EMA website.	No special official position has been adopted for now.	Slovenian Agency has not formulated a position on E-labelling yet. It is not to be expected that they form an official position soon. Their usual approach is to wait and see what the prevalent trend in the EU in general will be.	No further initiatives. Commercial initiative: MEDIATELY (https://mediately.co/si/about/) Available in seven European CEE countries: Slovenia, Croatia, Serbia, Czech Republic, Slovakia, Bulgaria and Romania Providing drug info, ICD-10 info and clinical and diagnostic tools in the user‘s local language on mobile and web, exclusively from independent, verified sources (EMA, national drug agencies, national insurance houses). Doctors and other HCPs are the current focus. For patients currently, PIL documents are now available as PDFs, they have information on price and surcharges and the coverage of medicines from insurance. The app also gives summary information what has changed in SmPC from the previous version.	home internet access: 70 % households with broadband connection: 74 % Internet usage for seeking health-related information: 50 %

Spain	Agency (AEMPS) provides an online database with current approved SmPC and PILs (CIMA) in PDF format that can be downloaded. For centralized products the Agency refers to EMA.	FARMAINDUSTRIA's position is rather positive and collaborates with the AEMPS in any related activity	No official position although they seem rather supportive of e-labelling	The AEMPS has just launched the possibility to read the bar codes on the carton of medicinal products with the i-phone/Android which would take the patient to key product information although not replacing the paper version for the moment. Farmaindustria is testing this one. The AEMPS is also working on developing the so called audio-PILs and audio-SmPCs to facilitate access to product information to blind and disabled people. All private initiatives always refer to the AEMPS data base (CIMA).	70% of households have internet access, 54% of Spanish use it on a daily basis
Sweden	LIF, trade Association of innovative pharma provides Fass.se containing PL, SmPC and information on medicines.. The product information is the text approved by the authorities, updated by the companies. New information has to be uploaded witin 10 days, important new info is “flagged”. Master data is updated several times by the hour. The PL can also be read out loud by the system and pharmacy staff can order a Braille version The website is available to all . It has 3 different target groups/channels (public. hcp and veterinary medicines. https://www.fass.se	LIF is encouraging E-labelling discussions - see right.	The MPA published SmPCs and PILs for national, MRP/DCP products on their website (www.mpa.se), available to the public. The updates are made within 24hrs after approval. For centrally approved products, the MPA has a link from their website to the EMA's website. No official position yet.	LIF has a working group dealing with electronic PLs. Among the goals is - advocacy among patient groups - advocacy among management in the companies - possible pilot	93 % of households have internet access 85 % of individuals use it on a daily basis

	The website is customized for use in mobile phones for all three channels. For patients, the PIL is displayed as first view section headings. Each section heading expands on a single click displaying the entire PIL text under the heading. This enables patients to search for information in a tailored fashion to meet their own needs. The mobile phone site also allow patients to check availability of the chosen medicinal products in all pharmacies (nearby using location, and by named Pharmacy search) There are also mobile applications for on-line and off-line use. The available apps are intended for health care personnel and not for the public.				
Switzerland	The agency provides an online database available to the public where all currently approved SmPCs and PILs for all medicinal products can be found and downloaded. This database is fully up to date. It also provides the possibility to search for products registered in Switzerland per INN or per company. Local labels do not have any links to company or industry websites or APPs which include product labelling electronically.	No position for now.	No position for now.	No initiatives.	91% of households do have internet access. 83% of individuals use it several times per week.

UK	Yes Main route is electronic Medicines Compendium (run by the small independent company, Datapharm). eMC updating systems rapid & easy to use, so up to date information available quickly after EMA/MHRA approval &/or request. MHRA also publish on their website, but system & functionaly weak so little used.	Supportive BGMA have successfully negotiated with MHRA for more electronic distribution of patient information materials in work sharing projects.	MHRA are supportive, for use in addition to PILs in packs (not as a replacement). Patient profile an important consideration per product. Electronic component will increase over time (starting with DHPCs) MHRA support & approve Apps and QR codes for individual products	BGMA co-ordinated work sharing projects for risk minimisation & educational materials (in close cooperation with MHRA). Between 7 & 12 companies taking part each time, can include originator. First all electronic distribution completed in mid 2017. BGMA common PIL project for high volume generics project in 2017. Did not succeed – due to different views between companies & no easy way to harmonise SMPCs between countries and companies.	High in young and working age people. Less in elderly.