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4 **Electronic product information for human medicines in the**
5 **EU – draft key principles**
6 A joint EMA–HMA–EC collaboration

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7

Comments should be provided using the online form:
https://ec.europa.eu/eusurvey/runner/ePI_Public_Consultation

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30 **List of abbreviations**

31	EC	European Commission
32	EEA	European Economic Area
33	EHR	Electronic health record
34	EMA	European Medicines Agency
35	ePI	Electronic product information
36	EU	European Union
37	HCP	Healthcare professional
38	HMA	Heads of Medicines Agencies
39	IDMP	Identification of Medicinal Products
40	ISO	International Organization for Standardization
41	MAH	Marketing authorisation holder
42	NCA	National competent authority
43	PDF	Portable document format
44	PI	Product information
45	PL	Package leaflet
46	SME	Micro, small or medium-sized enterprises
47	SmPC	Summary of product characteristics
48	SPOR	Substance, product, organisation and referential (EMA implementation of ISO IDMP standards)
49		

50 **Background**

51 In the European Union (EU), a medicine's product information (PI), which includes the summary of
52 product characteristics (SmPC, intended for healthcare professionals), labelling (outer and inner
53 packaging information) and package leaflet (PL, for patients/consumers and generally included as a
54 printed copy in the medicines package¹), is the pivotal source of regulated and scientifically validated
55 information that assists healthcare professionals in prescribing and dispensing the medicine and
56 informs patients and consumers about its safe use.²

57 A [report from the European Commission](#) (EC) in March 2017, and a subsequent [EMA action plan](#),
58 identified areas where the SmPC and PL could be improved to meet the needs of patients and
59 healthcare professionals and proposed actions to address these shortcomings. These wide-ranging
60 actions relate to enhancing readability, improving patient input in development and testing, promoting
61 best practices and developing an electronic format. Throughout 2018, a joint [EMA-HMA-EC](#)
62 [collaboration](#) has worked on the latter: identifying stakeholder needs from a future electronic PI for
63 medicines (ePI) and mapping ongoing initiatives in the field to create an overview of the current
64 landscape. The electronic format is the most pressing priority out of the actions from a public health
65 perspective as it will ensure patients have timely access to up-to-date information and coordination
66 among the many initiatives ongoing in the EU. The current scope of this work is all human medicines
67 authorised in the EU.

68 A workshop held at EMA on 28 November 2018 brought together patients/consumers, healthcare
69 professionals, industry stakeholders, academia, not-for-profit organisations and regulators to discuss
70 stakeholder needs and concerns, give an overview of the main ePI initiatives ongoing in the EU and
71 decide how to move forward with a common approach. The outcome of the workshop is the following
72 proposal for 'key principles' on ePI to be released for public consultation. These key principles do not
73 represent final guidance from EMA on ePI; they are intended, following the outcome of public
74 consultation, to form the basis of follow-up implementation plans for ePI.

75

¹ The legal requirement to include the PL in the packaging is laid down in Article 58 of the [Directive 2001/83/EC](#) which states: "The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging."

² The content of the SmPC, labelling and PL is described in Articles 11, 54, 55 and 59 of [Directive 2001/83/EC](#).

76 **Draft key principles on ePI in the EU**

77 The following key principles are intended, following a period of public consultation, to be agreed by
78 EMA, HMA, EC and representatives of patients, consumers, healthcare professionals and the
79 pharmaceutical industry. Future work on ePI will progress in alignment with these principles.

80 **1. Definitions**

81 Definitions of 'ePI' and 'common electronic standard' are intended to explain the meaning of these
82 terms as they are used in this initiative.

83 **1.1. ePI**

84 **Statement**

85 The following definition of ePI is proposed:

86 ePI is authorised, statutory product information for medicines (i.e. SmPC, PL and labelling³) in an
87 organised format created using the common EU electronic standard.⁴ ePI is adapted for electronic
88 handling and allows dissemination via the world wide web, e-platforms and print.

89 **Rationale**

90 There are many different interpretations of 'electronic product information.' Therefore, it is important
91 to clarify that for the purposes of this collaboration, ePI refers to a semi-structured format suitable for
92 electronic handling. Semi-structured means that ePI contains some structured elements (e.g. fixed
93 headings and vocabularies), and some unstructured elements (i.e. free text). Unstructured formats
94 such as PDF, Word or other unstructured text are not considered to be ePI because these do not
95 deliver the benefits to stakeholders outlined in these principles.

96 ePI refers to the structure of the PI and not its content.

97 **Implication**

98 By agreeing on an EU definition of ePI, there will be a harmonised understanding across the EU, which
99 will guide collaborative work to create ePI that meets the definition.

100 Implementation of the use of ePI, as described in the definition, will allow delivery of the benefits to
101 stakeholders as explained in the key principles 2.1 and 2.2. Such implementation will be carried out in
102 accordance with applicable European legislation. The development of ePI will not create new
103 requirements with regard to the content of the PI or a new legal obligation to use ePI. In addition, this
104 initiative should not be understood to change the interpretation of European legislation.

³ In certain procedures, Annex II of the marketing authorisation (manufacturer(s) responsible for batch release, conditions and requirements of the marketing authorisation, other conditions or restrictions as applicable) is provided electronically together with ePI.

⁴ See '1.2. Common EU electronic standard.'

105 **1.2. Common EU electronic standard**

106 **Statement**

107 ePI in the EU for all human medicines, including both centrally and nationally authorised medicines, will
108 be created using a common electronic standard. The following definition of a common EU electronic
109 standard for ePI is proposed:

110 A common standard for ePI in the EU refers to the technical features (including mark-up language,
111 controlled vocabularies and interoperability specifications) agreed by regulators and stakeholders. The
112 standard will be used to generate ePI that fulfils the agreed key principles.

113 **Rationale**

114 A common standard is necessary to provide consistent functionality of ePI for all medicines throughout
115 the EU. This will reflect the reality of interlinked medicines' regulatory systems among the European
116 medicines regulatory network as well as meeting the expectations of patients and healthcare
117 professionals who travel and work in several EU countries.

118 A common standard enables the generation and dissemination of electronic authorised information for
119 patients and consumers of medicines in the EU/EEA. It will not lead to a change in the interpretation of
120 applicable European legislation nor will it create new requirements with regard to the content of the PI
121 as described in EU legislation.

122 The aims of the common standard are:

- 123 • to create the technical foundation for the dissemination of trusted information in the electronic
124 world, which will allow patients/consumers and healthcare professionals an additional and tailored
125 approach on information for medicines according to his/her need and/or wish by using suitable
126 (electronic) output forms and platforms;
- 127 • to offer possibilities to streamline, simplify and speed up the regulatory process in the creation and
128 updating process (variation) of PI by using existing data of the SPOR (substance, product,
129 organisation and referential) process, both for regulators and the pharmaceutical industry.

130 Agreement of a common standard will avoid a situation where multiple different standards are
131 developed and used in different parts of the EU, which would generate unnecessary complexity,
132 impede access to information and require multiple interfaces between standards, restricting flow of
133 data.

134 **Implication**

135 The first step and pre-requisite for ePI implementation is the agreement of a common standard that
136 fulfils the requirements outlined in the key principles and is compatible with use at centralised and
137 national (through national competent authorities [NCA]) levels.

138 The common standard will be established considering the available technical features, including those
139 from EU Telematics projects. Further features, such as vocabularies and interoperability specifications
140 yet to be developed, may be added in later releases.

141 **2. Benefits for public health**

142 Regulators and stakeholders wish to work towards ePI in the EU because of the benefits this format
143 can offer for public health. While acknowledging that many future applications of ePI cannot currently

144 be predicted, the following principles outline the key benefits which constitute the fundamental reasons
145 underpinning this initiative.

146 **2.1. Expanding access to information on medicines as a public health** 147 **imperative**

148 **Statement**

149 ePI is a public health priority because it will expand the dissemination of unbiased, up-to-date,
150 regulator-approved PI for all medicines in the EU. ePI will support, among other functions:

- 151 • provision of the latest information on a medicine's safety, benefits and its conditions of use;
- 152 • better delivery of information so that the right information is available to the right
153 patient/consumer at the point of need;
- 154 • informed decision-making by patients/consumers and healthcare professionals.

155 **Rationale**

156 Unlike paper PLs contained in medicine packages, which are updated gradually as stocks of medicines
157 turn over, it will be possible to rapidly update ePI with the latest authorised information.

158 Patients/consumers and healthcare professionals using ePI can be fully confident that they hold the
159 latest information about benefits, risks and use.

160 In contrast to current PDF and unstructured text formats, ePI will enable wider availability on a range
161 of platforms. ePI is thereby expected to increase support to patients/consumers in informed decision-
162 making about their treatment and help them to adhere to their medication regimes, ultimately
163 contributing to optimal outcomes. ePI should also facilitate patient/consumer–healthcare professional
164 interactions and discussions about medicines.

165 The structured nature of ePI will offer new opportunities to better tailor product information to the
166 needs of individual patients/consumers. Also, because ePI can be handled electronically and read by
167 machines, ePI information can flow to other systems, such as electronic health records and
168 e-prescribing systems, facilitating targeted delivery of the right information to the right patient/
169 consumer at the point of need.

170 Availability of regulator-validated ePI will counterbalance unreliable and spurious claims about
171 medicines, often widely spread through online and other forums, by giving EU citizens an authoritative
172 source of scientific and evidence-based information on medicines.

173 **Implication**

174 EMA and NCAs should work towards ePI to fulfil their mission to protect public health. Implementation
175 will have as a goal the creation of ePI for all authorised human medicines in the EU/EEA.

176 ePI will be rapidly and continually updated as soon as changes to the SmPC and PL are authorised by
177 the regulatory authorities. The most up-to-date ePI version should be always easily available.

178 To achieve this principle, ePI should be made available through various technologies and applications,
179 including mobile scanning technology (such as a 2D barcode) on the medicine package.⁵ Correct ePI
180 depends on the medicine batch: some parts of the ePI may be applicable to all batches and some only

⁵ EMA and CMDh guidance on use of barcodes is available at: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-reference-documents-guidelines> and <http://www.hma.eu/90.html>

181 to specific batches (e.g. when excipients change). Therefore the need for the correct ePI to be supplied
182 for the medicine batch should be taken into consideration.

183 **2.2. Accessibility to patients/consumers with diverse abilities**

184 **Statement**

185 ePI will facilitate creation of PI that is accessible to everyone, including patients/consumers with print
186 impairments such as blind and partially sighted people (e.g. use of large font size) and those with low
187 literacy levels (e.g. audible formats). ePI on the web will be accessible to screen readers, convertible to
188 large font and amenable to other accessible formats.

189 **Rationale**

190 Current PDF and print copy formats of PI do not well serve all citizens equally, given the wide range of
191 abilities throughout society.

192 In contrast with current PDF and print copy formats of the PI, the availability of ePI will allow third-
193 parties, such as companies, not-for-profit organisations or patient/consumer groups, to convert the PI
194 into accessible formats.

195 **Implication**

196 ePI will be accessible by design.

197 **3. Existing legislative framework**

198 Implementation and use of ePI must comply with the legislation in force. These principles underline
199 some of the legislation relevant to ePI.

200 **3.1. Complementing paper package leaflet**

201 **Statement**

202 ePI will not supersede or negate the requirement of the pharmaceutical legislation (Article 58 of
203 [Directive 2001/83/EC](#)¹) to include a PL in the packaging of all medicines or directly convey all
204 information required (by Articles 59 and 62 of the Directive) on the outer or immediate packaging.

205 Since the current legislation does not require the use of an electronic version of PI, the use of ePI will
206 not constitute a new legal obligation.

207 **Rationale**

208 The ePI is intended to expand the formats in which PL is available and not to remove or substitute the
209 currently available paper format. PLs are a valuable tool presented directly in the medicines package
210 and therefore provided to all patients/consumers when they open their medicine. The paper PL is
211 particularly important for patients/consumers with low digital literacy (low ability to use digital devices
212 effectively) or limited internet access.

213 **Implication**

214 Generation of ePI does not involve any change to the content of the PI. ePI generation will be
215 performed in addition to the current inclusion of the PL in the medicine package. The use of ePI will be
216 a recommended innovation; however it is not mandatory.

217 The paper PL should include a statement directing to the ePI as the most up-to-date version of the PL.

218 **3.2. Open access to regulator-approved information only**

219 **Statement**

220 ePI is intended for the delivery of regulator-approved medicine PI only. The content of ePI should be
221 identical to the latest version of the PI approved by regulatory authorities. ePI will not be used for
222 delivery of promotional information.

223 ePI should always be published as open data, freely accessible for use and reuse.

224 **Rationale**

225 The development and implementation of ePI will be carried out in accordance with applicable EU
226 legislation; therefore the content of ePI will be approved as a result of regulatory procedures currently
227 prescribed in the legislation (or as will be amended by any future legislation). Accordingly, no
228 additional information — either for promotional or other purposes — can be included in the ePI.

229 The [European Interoperability Framework](#) (underlying principle 2: openness) describes the principle of
230 openness as the idea that all public data should be freely available for use and reuse by others, unless
231 restrictions apply.

232 **Implication**

233 Since, by use of ePI, stakeholders must comply with the applicable EU legislation, which strictly
234 regulates the content of PI and excludes any element of a promotional nature, the rights of patients
235 and consumers to have access to validated, non-promotional information will be maintained.

236 **3.3. Data protection**

237 **Statement**

238 ePI itself will not include any personal data.

239 In any event where processing (e.g. collecting or handling) of personal data may occur in relation to
240 the implementation and use of ePI, for example in the context of a mobile application developed for
241 the use of patients to access ePI, personal data processing must be in accordance with applicable
242 European data protection legislation. This includes, in particular [Regulation \(EU\) 2016/679 \(GDPR\)](#) and
243 [Regulation \(EU\) 2018/1725](#) applicable to EU institutions.

244 **Rationale**

245 All parties involved in the development and use of ePI including the members of the European
246 medicines regulatory network, MAHs, other companies and healthcare professionals are reminded of
247 their obligation to comply with applicable European data protection legislation, which includes
248 Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725.

249 **Implication**

250 All stakeholders processing personal data in relation to ePI must ensure full compliance with the
251 applicable European data protection legislation.

252 **4. Processes**

253 The following principles relate to the implementation of ePI, including processes, roles and
254 responsibilities.

255 **4.1. Governance**

256 **Statement**

257 It is envisaged that, eventually, ePI format will be used for the PI of all human medicines authorised in
258 the EU by all EU authorities from the point of submission and throughout the evaluation process.

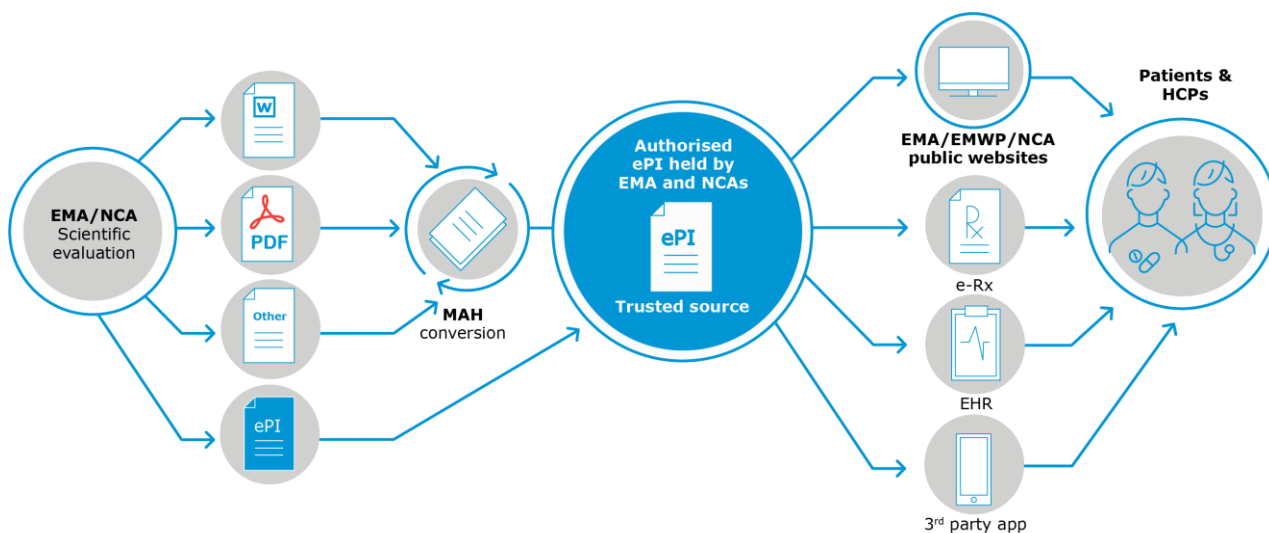
259 However, in the short and medium term, regulatory authorities may decide to implement ePI using a
260 step-wise approach: ePI may either be used throughout the assessment, or alternatively, assessment
261 may be performed as is done currently, and the PI converted to ePI once the regulatory procedure is
262 complete.

263 ePI will be made available to users (patients/consumers and healthcare professionals) through
264 websites at EMA level and if available, Member State level.

265 ePI data will be made available for use in other e-health systems, such as electronic health records and
266 e-prescribing systems.

267 ePI will also be available for use by third-parties, who can reproduce ePI and make it available to
268 patients and healthcare professionals.

269 **Figure 1.** Proposed model for ePI process (subject to change following feasibility analysis once ePI
 270 project is started). Following regulatory evaluation, if final PI is not already in ePI format, it is
 271 converted to ePI by the MAH using a conversion tool. As currently done for the final PI in PDF, the
 272 final ePI will be accompanied by a declaration from the MAH confirming that the converted version
 273 is identical in content to the one approved (in Word or other format). ePI for both nationally and
 274 centrally authorised products (NAPs and CAPs) can be accessed from the European medicines web
 275 portal (EMWP) and NCA public websites. ePI can be used with systems for e-prescribing (e-Rx)
 276 and electronic health records (EHR). Data can be accessed by third-party providers for example,
 277 for use in patient/consumer apps.



278

279 **Rationale**

280 Currently, the responsibility for creating the final PI files after the content is approved by the regulator
 281 lies with the MAH, and this will also be the case for ePI.

282 Where authorities are not using ePI throughout the assessment, conversion to ePI may take place once
 283 the evaluation is completed.

284 The regulator should hold ePI data, as a trusted source for reliable medicines information. The NCA in
 285 each country will store and handle ePI in their jurisdiction. In addition, it is envisaged that a pan-
 286 European medicines web portal could provide a central point for access of ePI for all centrally and
 287 nationally authorised medicines.

288 **Implication**

289 During implementation, it is anticipated that several scenarios will co-exist in the EU in the short to
 290 medium term.

- 291 1. No ePI: authorisation is performed as is done today and ePI format is not yet generated for the
 292 authorised medicine;
- 293 2. Conversion to ePI: authorisation is performed as is done today and once the procedure is
 294 complete, PI is converted to ePI;
- 295 3. Submission of ePI: PI is submitted to the authorities in electronic format, evaluated in this format,
 296 and is therefore already in ePI format once the evaluation procedure is complete.

297 **4.2. Flexibility in implementation**

298 **Statement**

299 All stakeholders, including pharmaceutical companies and regulators, will commit to implementation of
300 the common electronic standard for creation of ePI for all EU medicines. However, it is recognised that
301 timelines and processes for implementation should be flexible to allow for variations in resources and
302 priorities. A roadmap will be proposed by HMA and EMA to guide implementation.

303 **Rationale**

304 The size and complexity of the task of creating ePI for European medicines is such that it is unrealistic
305 to envisage implementation throughout the EU simultaneously.

306 In addition, handling ePI may be a significant burden for some Member States as well as certain
307 companies such as micro, small or medium-sized enterprises (SMEs) and companies producing generic
308 medicines.

309 **Implication**

310 Once a common standard and governance process are established, stakeholders must plan for their
311 implementation in their jurisdictions according to a roadmap, including timelines, determined at HMA
312 and EMA level.

313 Some early-adopter Member States may begin using ePI for their authorised medicines as soon as
314 possible, whereas other Member States may have different priorities for implementation. Also, some
315 Member States may wish to implement ePI throughout the medicines authorisation process and use it
316 as a vehicle for exchanges on the PI with the applicant during the assessment, whereas other Member
317 States may wish to have the SmPC, labelling and PL converted to ePI format only once the evaluation
318 process has been finalised.

319 Support and flexibility for pharmaceutical companies in implementation will also be considered.

320 Flexible implementation should also include planning for conversion of existing PIs of authorised
321 medicines to the new ePI format. This could be incorporated into post-authorisation procedures.

322 Flexibility will allow for divergent mechanisms and timelines for implementation, as these will still
323 ultimately allow a harmonised approach for ePI across the EU.

324 **5. EU context**

325 These principles describe how ePI fits into the multilingual EU environment and interacts with other
326 ongoing initiatives.

327 **5.1. Multilingual ePI**

328 **Statement**

329 ePI should support all official EU languages and Icelandic and Norwegian so that EU citizens will be
330 able to read ePI in their preferred language when authorised ePI in that language is available.

331 **Rationale**

332 The PI for a centrally authorised medicine is available in all official EU languages (plus Norwegian and
333 Icelandic) and the PI for a nationally authorised medicine is available in one or more official
334 language(s) of the Member State where the medicine is placed on the market.

335 National authorities decide in which official language(s) PI will be provided in their countries for
336 nationally authorised products.

337 ePI should also be possible in these languages, as applicable. Availability of ePI in patients'/consumers'
338 and healthcare professionals' own language, where available, facilitates full understanding.

339 PI may be needed in non-EU languages in some Member States. National authorities are responsible
340 for additional non-EU languages and these are not currently in the scope of the ePI initiative.

341 **Implication**

342 ePI design and implementation must, from the start, ensure capability to provide PI in all official EU
343 languages as well as Icelandic and Norwegian.

344 **5.2. Interoperability with EU and global initiatives**

345 **Statement**

346 ePI will interface and interact with many ongoing and foreseen eHealth initiatives. eHealth and related
347 services should work together, within and across organisations or domains. ePI interoperability with
348 cross-border prescription, electronic health records, the future European medicines web portal,
349 pharmacovigilance systems, [SPOR data management services](#), a future [European common data model](#)
350 and national ePI systems must be considered in the design of EU ePI. Use of ePI in both an EU and
351 global context should also be taken into account.

352 **Rationale**

353 This collaboration takes place in the context of today's ongoing digital transformation of healthcare.
354 Digital tools and services such as electronic health records, e-prescribing, mobile platforms and
355 wearables gather data and disseminate knowledge, yet maximising the benefits of digital technologies
356 to public health will depend on ensuring the flow of data through interconnected health systems to
357 deliver point-of-need access to the information that matters to patients/consumers and healthcare
358 professionals.

359 The EC eHealth policy anticipates that 'person-centred approaches' can ensure improved patient well-
360 being and quality of care and contribute to sustainable health systems. Patients/consumers and
361 healthcare professionals need information from the PI at various points in the treatment journey,
362 including information on use and administration of the medicine, how to recognise possible side effects
363 and how to act in the light of new safety data. Interoperability will ensure that this information can be
364 delivered to patients/consumers at the point of need through interaction of the ePI with electronic
365 health records and e-prescriptions.

366 The [European Interoperability Framework](#) recommends (recommendation 9) ensuring data portability,
367 namely that data is easily transferable between systems and applications supporting the
368 implementation and evolution of European public services without unjustified restrictions, in
369 accordance with the legal framework.

370 **Implication**

371 ePI will be interoperable by design with eHealth initiatives and EU Telematics projects, and will
372 consider national infrastructures and global health standards.