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Delivered electronically to:
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Opinion based on the green paper on mobile Health ("mHealth") (COM(2014) 219 final

First of all, a lot of thanks to DG Communications Networks, Content and Technology (CNECT) for organising this important consultation

This opinion represents an opinion of an individual citizen, not any legal entity.

- This opinion does not contain:
- any business secrets
 - any trade secrets
 - any confidential information.

This opinion is public.
DG Communications Networks, Content and Technology (CNECT) can add the PDF file of this opinion to a relevant web page.

Annex 1 holds information about previous consultations.
Annex 2 holds information about disclaimers and copyright.

Best Regards,

Jukka S. Rannila
citizen of Finland
signed electronically

44
45 **Part 1: General notes before answering the questions (COM(2014) 219 final)**

46
47 **Previous consultations organised by the European Commission**

48
49 In Annex 1 is a list of previous consultation addressed mainly to different DGs.

50
51 I do not know about the cooperation between different DGs and between different units inside
52 specific DGs. However, it can be concluded from the previous consultation answers, that different
53 consultations organised by the European Commission (Units / DGs) have highlighted different
54 aspects of digitalisation (of everything).

55
56 Possibly previous consultations could be useful for evaluating some mobile health proposals.

57
58 **Some contributions from the previous consultations?**

59
60 One of the main contributions from the previous consultations has been simplified descriptions of
61 information technology. In many consultation documents, there has been quite ambiguous
62 descriptions about information technology in different application fields.

63
64 **This consultation / green paper on mobile Health ("mHealth") (COM(2014) 219 final)**

65
66 In reality mobile health applications will be a new layer for existing / current systems. Generally
67 speaking, there are hundreds/thousands of different information technology applications in the
68 member states (EU).

69
70 Some member states (e.g. Estonia) have been able to establish their new information systems with a
71 limited number of previous / existing information systems, and their new information systems have
72 been in the internet-based systems from the beginning. E.g. in Finland the current Government has
73 been very interested about the X-Road¹ system(s) used in Estonia.

74
75 Based on the Estonian-Finnish discussion it can be said, that cooperation of the Finnish information
76 systems with possible Finnish X-Road will be quite difficult, since Finland has so many old
77 systems. So, possible Finnish mobile health applications may demand a lot of work – legislative,
78 administrative and technical work.

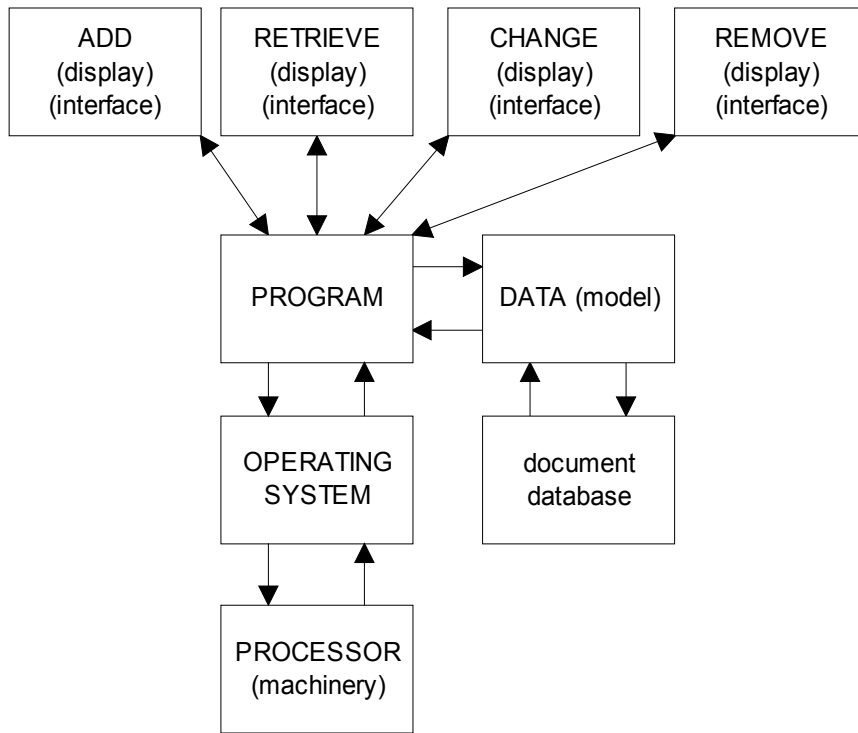
79
80 **Mobile health – explicating the nature of an application field**

81
82 One simple conception of information technology solutions is the following figure.

83
84 The figure gives us four basic functions: add, retrieve, change and remove. Then there are databases
85 and documents used in different systems. Users use different displays (interfaces). Different
86 systems need administration (also maintenance) for keeping a system functional. Then there is
87 communication (also standards) for direct and indirect usage of an information system.

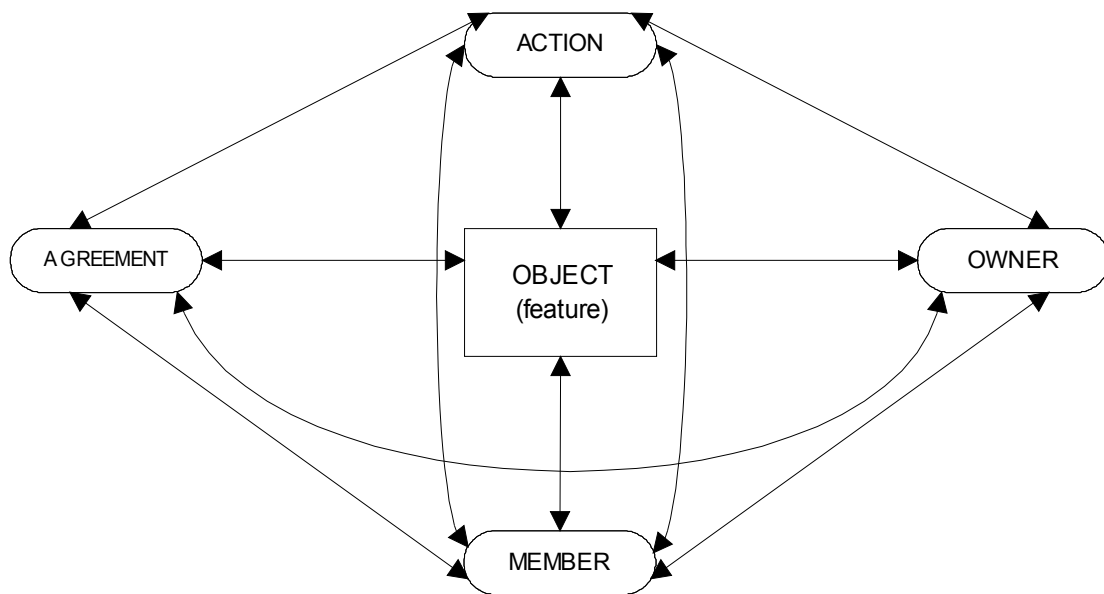
1 <https://www.ria.ee/x-road-factsheets-2014/>, X-Road factsheets 2014, the link worked on 24 June 2014

88 It can be said, that in all parts of an information systems there can be open solutions and closed
89 solutions.



90
91

92 The mentioned linkages linkages between ownership, agreements and membership can also be
93 divided to two actions: distribution and usage. There is nothing new on the previous explanations.
94 However, the difference between distribution and usage should be as clear as possible.
95



96

97

98 In short:

- 99 * the world is full of different objects (things)
 100 * objects can be nowadays be digital in all phases
 101 * someone owns some objects
 102 * usage can be based on ownership, agreements and membership
 103 * the linkages between ownership, agreements and membership can be very complex
 104 * the linkages between ownership, agreements and membership can change very often.

105

106 Next table gives us some possibilities for assessing possibilities for open solutions and closed
 107 solutions.

108

	Owner? Member? Agreement?	OPEN	CLOSED
1. Device / Machinery			
2. Operating system			
3. Program(s)			
4. Data models / Conceptual models			
5. Documents			
6. Databases			
7. Communications			
8. Retrieve / Interface / Display			
9. Add / Interface / Display			
10. Remove / Interface / Display			
11. Change / Interface / Display			

109

110 It can be said, that this consultation (mobile health) is rather general, and there are possibilities for
 111 assessing different combinations of different features for mobile health applications.

112

113 In the previous consultations I have advocated following solution as the maximum solution:

- 114 * public sector institute owns the machinery and processor of the information system
 115 * the machinery and processor are based on relevant open standards
 116 * the operating system is based on an open-source solution
 117 * public sector institute owns the source code of the information system
 118 * public sector institute owns the database of the information system
 119 * the database is based on open-source solution and on relevant open standards
 120 * public sector institute owns all data in the information system.

121
122 Naturally, there can be solutions, which are not based on the maximum solution.
123

124 **Proposal 1: The European Commission could organise answers of this consultation**
125 **based on different combinations explicated in the consultation answers, i.e. Owner,**
126 **Member, Agreement, Open, Closed and different basic functions (Add, Retrieve,**
127 **Change, Remove).**

128
129 **Note: The relations between different aspects of information systems can result rather**
130 **complicated network(s).**

131
132 **Actual reality / Different standards and standards versions**

133
134 Previously I have advocated open standards for mobile health systems.

135
136 It is quite normal situation in the information technology field that there is competing standards for
137 some application field. Therefore there is all the time ongoing “standards wars” or “format wars”.
138 The information technology standards tend to be interrelated and one “standards war” or “format
139 war” can lead to another similar situation.

140
141 Therefore, there should be serious vigilance when assessing different standards and “standards” in
142 some application field, e.g. mobile health.

143
144 In the previous consultations the European Commission (DG Competition) has organised Market
145 Tests based on commitments provided by different companies, e.g. Microsoft, IBM, Reuters and
146 VISA. In some cases there has been a (near) monopoly situation, and in some cases different
147 standards has been (so called) de facto standards. Usage of some de facto standards demand e.g.
148 licence fees or other monetary requests, and the European Commission (DG Competition) has been
149 active to assess the monopoly/antitrust aspects of some de facto standards.

150
151 **Proposal 2: European Commission (DG Communications Networks, Content and**
152 **Technology, CNECT) could gather information about current standards used in the**
153 **mobile health application field(s).**

154
155 There might be some de facto standards, which may be hindering competition in some mobile
156 health application field(s).

157
158 **Proposal 3: The European Commission (DG Communications Networks, Content and**
159 **Technology, CNECT) could assess the (near) monopoly situation with current**
160 **standards used in the mobile health application field(s).**

161
162 **Proposal 4: The need for some antitrust actions has to be assessed carefully after the**
163 **gathering the information about different standards in the mobile health application**
164 **fields – especially de facto standards.**

165

166 Previously I have advocated open standards, even though in some cases open standards are not de
 167 facto standards. In practice public sector has very important role, when some standards are
 168 competing in the market place. Because public sector has a considerable buying power due to its
 169 purchasing (power), and therefore public sector can sometimes direct markets to certain standards.
 170

171 However, creating a new standard means actual both administrative and technical work, and in
 172 some cases creating a new standard can last quite long. There are a lot of different standard setting
 173 organisations (SDO), and one comprehensive list is provided ² for us by ConsortiumInfo.org.
 174

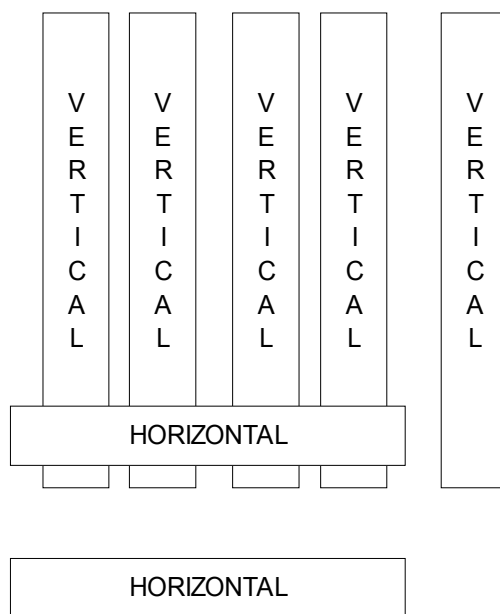
175 **Proposal 5: The European Commission (DG Communications Networks, Content and**
 176 **Technology, CNECT) could assess current standardisation efforts of different standard**
 177 **setting organisations (SDOs).**

178
 179 **Proposal 6: The European Commission (DG Communications Networks, Content and**
 180 **Technology, CNECT) could fund development of some important standard(s).**

181

182 **Supporting and/or developing different standard types**

183



184

185

186 One of the main themes can be division standards: horizontal standards and vertical standards. What
 187 this means? Generally speaking, different ICT solutions will implement a large collection of
 188 different standards: open standards and closed standards. In many cases, different ICT solutions do
 189 not work together and this might not constitute a problem. However, in many cases different ICT
 190 solutions has to work together seamlessly – possibly without further problems.
 191

191

192 **Proposal 7: There could be separation of horizontal standards and vertical standards.**

² <http://www.consortiuminfo.org/links/linksall.php>, Standard Setting Organizations and Standards List

193 **Proposal 8: There could be different standardisation efforts to horizontal standards**
 194 **and vertical standards.**

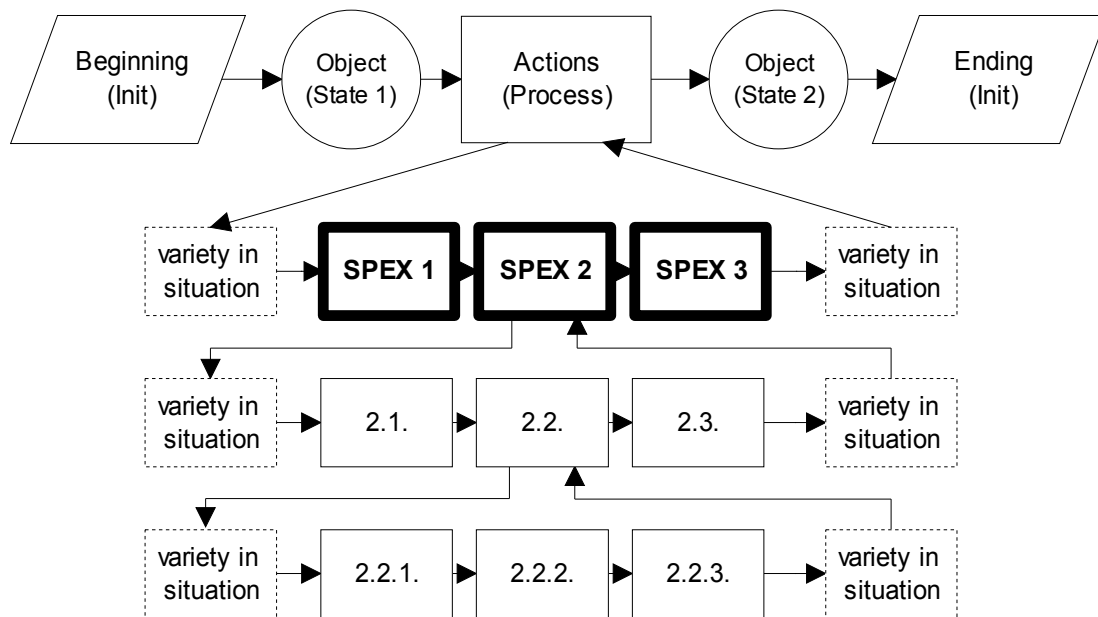
195
 196 **Proposal 9: Developing (and possible funding of development) horizontal standards**
 197 **should favoured in the development of new and/or revised standards.**

198
 199 An example can be different email standards. There are numerous email systems developed with
 200 numerous technologies (vertical), but the cooperation between numerous email systems is possible
 201 with different (horizontal) email standards.

202
 203 **Opinion: The number of redundant standardisation efforts should be minimal.**

204
 205 **Standardisation of interfaces for customers (citizens)**

206
 207 In previous consultations I have advocated standardisation of interfaces. There are different
 208 processes (Beginning → Actions → Ending), which can be described in different levels of details.
 209



210
 211
 212 There can be highly detailed points in different processes (SPEX), which could be standardised.

213
 214 **Proposal 10: There could be a project for modelling different customer (care)**
 215 **processes.**

216
 217 **Proposal 11: Some parts of the customer (care) processes could be standardised for**
 218 **customer interfaces (SPEX).**

219
 220 **Proposal 12: Some standardised customer interfaces (SPEX) could be used for having**

221 **better customer (care) processes.**

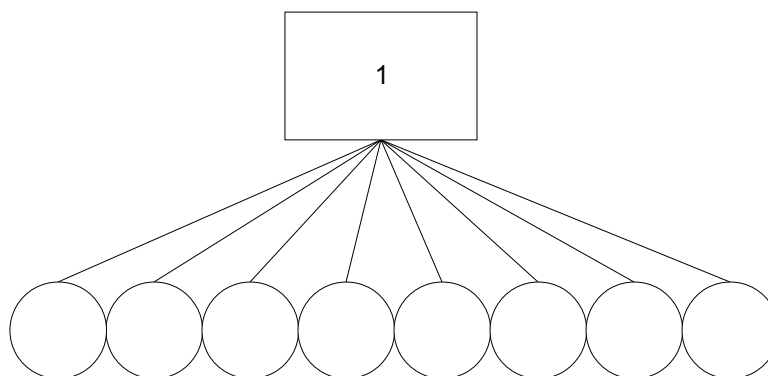
222

223 It can be noted, that different actors can naturally have other non-standardised interfaces for
224 customer(s) (care), and there is nothing wrong with that approach. Also, we have to assess the need
225 for several customer (care) interfaces. In other words, different stakeholder groups need different
226 interfaces, and identity proofing is not an exception of this situation.

227

228 In the previous consultations documents I have explicated the need for standardisation of some
229 interfaces. In practical reality, there can be different information technology applications for the
230 same operations, e.g. standardised interfaces for patients. It could be feasible to create different
231 standardised interfaces, which can be implemented with different technologies.

232



233

234

235 **Proposal 13: There could be a project for analysing the quality and the quantity of**
236 **different interfaces for different stakeholder groups, e.g. patients as one group.**

237

238 **Proposal 14: European Commission can advocate standardised user interfaces in**
239 **different levels.**

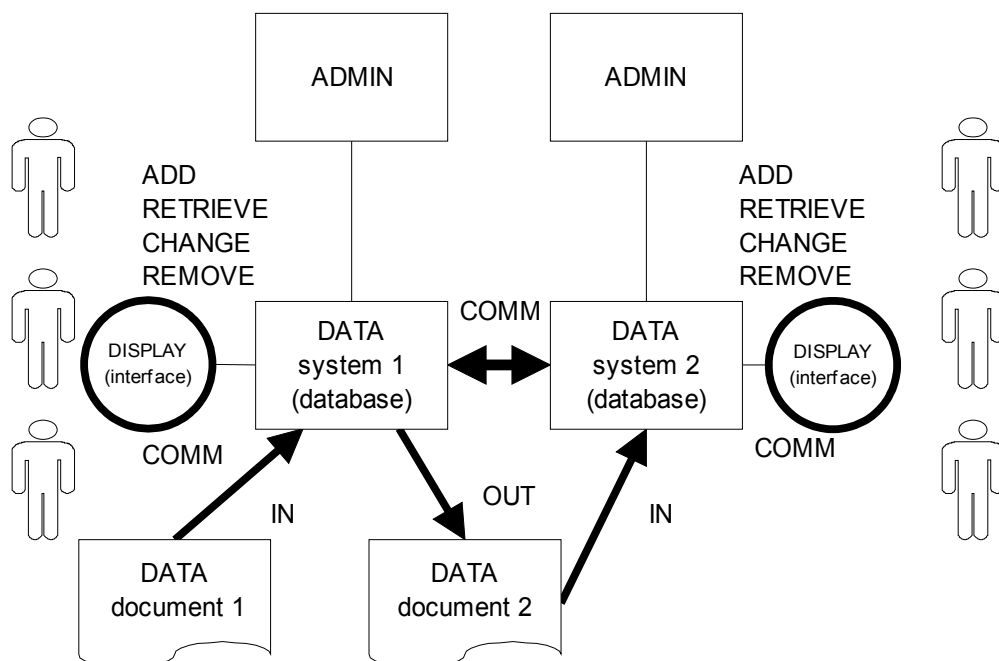
240

241 Naturally, there can be even tens of different user interfaces depending on the nature of different
242 systems. The actual reality is very complex. In practical terms there are several situations:

- 243 * systems must communicate directly with each other
- 244 * there will be several communications methods for direct communication
- 245 * there are different standards for direct communication
- 246 * data in the system is added by processing different documents
- 247 * data from the system is extracted and loaded to different documents
- 248 * there are different standards for different documents
- 249 * there will be several types for different documents
- 250 * there are several displays / interfaces to system(s)
- 251 * there are several user groups.

252

253 The following figure tries to explicate these features of information systems.



254
255

256 One solution can be standardisation efforts for different interfaces in several systems. The European
257 Commission could work with global and regional partners for creating standardised user interfaces
258 for different stakeholders. These standardised user interfaces could then be implemented by
259 different information systems.

260

261 **Proposal 15: The Commission can could support work, which rigorously develops and**
262 **tests different interfaces for different purposes.**

263

264 In reality there can be some applications (e.g. A, B, C) for the same operations, and there can be
265 different providers for the same solutions. IF every solution has a different interface, there can be a
266 serious hindrance with the needed education for a new interface. When there are some standardised
267 interfaces (SPEX), the efforts for learning of a new interface can be minimised.

268

269 **Part 2: Answering the questions (COM(2014) 219 final)**

270

271 **Question (COM(2014) 219 final, page 9):**

272 Which specific security safeguards in mHealth solutions could help to prevent unnecessary and
273 unauthorised processing of health data in an mHealth context?

274

275 **Proposal 16: Like mentioned before, standardisation of some interfaces could help**
276 **different stakeholder groups, and some security interfaces could be standardised.**

277

278 **Question (COM(2014) 219 final, page 9):**

279 How could app developers best implement the principles of “data minimisation” and of “data
280 protection by design, and “data protection by default” in mHealth apps?

281

Proposal 17: One option is to standardise models in databases.

282

283

284

Proposal 18: One option is to standardise documents, which are distributed between systems.

285

286

287

NOTE: e.g. in Finland different models in different database systems have been cause for serious problems when trying to create actual cooperation with different systems.

288

289

Question (COM(2014) 219 final, page 10):

What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU whilst complying with legal and ethical requirements?

292

293

Proposal 19: One option is to create "Big Data" licences for different application fields.

294

295

Question (COM(2014) 219 final, page 11):

Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?

298

299

Opinion: I dont know the situation in all member states.

300

301

Question (COM(2014) 219 final, page 11):

Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts; if yes, why and how?

304

305

Opinion: I dont know the situation in all member states.

306

307

Question (COM(2014) 219 final, page 13):

What good practices exist to better inform end-users about the quality and safety of mHealth solutions (e.g. certification schemes)?

310

311

Opinion: I dont know the situation in all member states.

312

313

Question (COM(2014) 219 final, page 13):

Which policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?

316

317

Opinion: I dont know the situation in all member states.

318

319

Proposal 20: Technically speaking, there should be different testing environments

320

and/or test suites for creating efficient information systems.

321

322

Proposal 21: Different testing environments and/or test suites could be the basis for

323

information systems procurement.

324

325

326 How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?
327

328

329 **Proposal 22: Like said before, assessing current standardisation efforts can be the**
330 **starting point for creating mHealth solutions.**

331

332 **Opinion: The amount of redundant standardisation should be minimal.**

333

334 **Question (COM(2014) 219 final, page 14):**

335 Do you have evidence on the uptake of mHealth solutions within EU's healthcare systems?
336

337

338 **Opinion: I dont know the situation in all member states.**

339

340 **Question (COM(2014) 219 final, page 14):**

341 What good practices exist in the organisation of healthcare to maximise the use of mHealth for
342 higher quality care (e.g. clinical guidelines for use of mHealth)?
343

344

345 **Opinion: I dont know the situation in all member states.**

346

347 **Question (COM(2014) 219 final, page 14):**

348 Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare
349 costs in the EU?
350

351

352 **Opinion: I dont know the situation in all member states.**

353

354 **Question (COM(2014) 219 final, page 14):**

355 What policy action could be appropriate at EU, as well as at national, level to support equal access
356 and accessibility to healthcare via mHealth?
357

358

359 **Proposal 23: Like said before, standardisation of some interfaces could be the starting**
360 **point for mHealth systems.**

361

362 **Proposal 24: European Commission could gather information of the used standards in**
363 **national (mHealth) systems.**

364

365 **Proposal 25: Based on the analysis of national (mHealth) system standards there could**
366 **be a decision of developing different standards in the European Union level.**

367

368 **Opinion: The amount of redundant standardisation should be minimal.**

369

370 **Question (COM(2014) 219 final, page 15):**

What, if anything, do you think should be done, in addition to the proposed actions of the eHealth
Action Plan 2012-2020, in order to increase interoperability of mHealth solutions?
371

372

373 **Opinion: This question has been answered before.**

374

371 **Question (COM(2014) 219 final, page 15):**

372 Do you think there is a need to work on ensuring interoperability of mHealth applications with
373 Electronic Health Records? And if yes by whom and how?

374

375 **Opinion: The Finnish case of interoperability between different (e.g. electronic health
376 systems) systems is an example of a disastrous situation.**

377

378 **Opinion: Standardisation has been proposed in previous proposals.**

379

380 **Question (COM(2014) 219 final, page 16):**

381 Which mHealth services are reimbursed in the EU Member States you operate in and to what
382 extent?

383

384 **Opinion: I dont know the situation in all member states.**

385

386 **Question (COM(2014) 219 final, page 16):**

387 What good practice do you know of that supports refund of mHealth services (e.g. payer-
388 reimbursement model, fee-for-a service model, other)? Please give evidence.

389

390 **Opinion: I dont know the situation in all member states.**

391

392 **Question (COM(2014) 219 final, page 17):**

393 What recommendations should be made to mHealth manufacturers and healthcare professionals to
394 help them mitigate the risks posed by the use and prescription of mHealth solutions?

395

396 **Opinion: This has been answered before.**

397

398 **Question (COM(2014) 219 final, page 17):**

399 Could you provide specific topics for EU level research & innovation and deployment priorities for
400 mHealth?

401

402 **Opinion: I dont know the situation in all member states.**

403

404 **Question (COM(2014) 219 final, page 18):**

405 How do you think satellite applications based on EU navigation systems (EGNOS and Galileo) can
406 help the deployment of innovative mHealth solutions?

407

408 **Opinion: I dont know the situation in all member states.**

409

410 **Question (COM(2014) 219 final, page 18):**

411 Which issues should be tackled (as a priority) in the context of international cooperation to increase
412 mHealth deployment and how?

413

414 **Proposal 26: Previously mentioned analysis of systems in national level may result
415 ideas for international cooperation, e.g. standardisation possibilities.**

416

417 **Question (COM(2014) 219 final, page 18):**418 Which good practice in other major markets (e.g. US and Asia) could be implemented in the EU to
419 boost mHealth deployment?

420

421 **Opinion: I dont know the worldwide situation.**

422

423 **Question (COM(2014) 219 final, page 18):**424 Is it a problem for web entrepreneurs to access the mHealth market? If yes, what challenges do they
425 face? How can these be tackled and by whom?

426

427 **Proposal 27: Like said before, the licences for different functions in information**
428 **systems has to be assessed very critically.**

429

430 **Proposal 28: The used standards should be public and free.**

431

432 **Question (COM(2014) 219 final, page 18):**433 If needed, how could the Commission stimulate industry and entrepreneurs involvement in
434 mHealth, e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership
435 on Active and Healthy Ageing?

436

437 **Opinion: I dont know the situation in all member states.**

438

439 **Proposal 29: The Commission could directly fund and support different standard**
440 **setting organisations bases on the analysis of different standards in the European**
441 **Union level and in the national level.**

442

443

444

445 **Good luck !!!**

446

447 This opinion is quite limited. Hopefully, there are other constructive ideas presented in other
448 opinions. This remains to be seen.

449

450

ANNEX 1

451

452

453 My opinions to the previous and relevant consultations – there consultations were mostly organised
454 by the Commission of the European Union. General page to all consultations – both in English and
455 in Finnish: <http://www.jukkarannila.fi/lausunnot.html>

456

457

458 EN: Opinion 1: Review of the rules on access to documents

459 http://www.jukkarannila.fi/lausunnot.html#nro_1

460

461 EN: Opinion 2: Schools for the 21st Century

462 http://www.jukkarannila.fi/lausunnot.html#nro_2

463

464 EN: Opinion 3: The future of pharmaceuticals for Human use in Europe- making Europe a Hub for
465 Safe and Innovative medicines

466 http://www.jukkarannila.fi/lausunnot.html#nro_3

467

468 EN: Opinion 5: Consumer Scoreboard, Questionnaire for stakeholders

469 http://www.jukkarannila.fi/lausunnot.html#nro_5

470

471 EN: Opinion 6: Consultation on a Code of Conduct for Interest Representatives

472 http://www.jukkarannila.fi/lausunnot.html#nro_6

473

474 EN: Opinion 8: European Interoperability Framework, version 2, draft

475 http://www.jukkarannila.fi/lausunnot.html#nro_8

476

477 EN: Opinion 9: CAMSS: Common Assessment Method for Standards and Specifications, CAMSS
478 proposal for comments

479 http://www.jukkarannila.fi/lausunnot.html#nro_9

480

481 EN: Opinion 15: Collective Redress

482 http://www.jukkarannila.fi/lausunnot.html#nro_15

483

484 EN: Opinion 17: Opinion to Antitrust Case No. COMP/C-3/39.530

485 http://www.jukkarannila.fi/lausunnot.html#nro_17

486

487 EN: Opinion 18: Opinion Related to the Public Undertaking by Microsoft

488 http://www.jukkarannila.fi/lausunnot.html#nro_18

489

490 EN: Opinion 19: Official Acknowledgement by the Commission

491 http://www.jukkarannila.fi/lausunnot.html#nro_19

492

493

- 494 EN: Opinion 20: SECOND Opinion Related to the Public Undertaking by Microsoft
495 http://www.jukkarannila.fi/lausunnot.html#nro_20
496
- 497 EN: Opinion 21: Opinion about the European Interoperability Strategy proposal
498 http://www.jukkarannila.fi/lausunnot.html#nro_21
499
- 500 EN: Opinion 23: Public consultation on the review of the European Standardisation System
501 http://www.jukkarannila.fi/lausunnot.html#nro_23
502
- 503 EN: Opinion 27: Public Consultation on the Modernisation of EU Public Procurement Policy
504 http://www.jukkarannila.fi/lausunnot.html#nro_27
505
- 506 EN: Opinion 28: Consultation on the Europe 2020 Project Bond Initiative
507 http://www.jukkarannila.fi/lausunnot.html#nro_28
508
- 509 EN: Opinion 30: Internet Filtering
510 http://www.jukkarannila.fi/lausunnot.html#nro_30
511 NOTE: Organised by the European Committee for Standardization (CEN) ³
512
- 513 EN: Opinion 32: COMP/C-3/39.692/IBM – Maintenance services
514 http://www.jukkarannila.fi/lausunnot.html#nro_32
515
- 516 EN: Opinion 34: REMIT Registration Format
517 http://www.jukkarannila.fi/lausunnot.html#nro_34
518 NOTE: Organised by The Agency for the Cooperation of Energy Regulators (ACER) ⁴
519
- 520 EN: Opinion 35: Exploiting the employment potential of the personal and household services
521 http://www.jukkarannila.fi/lausunnot.html#nro_35
522
- 523 EN: Opinion 37: CASE COMP/39.654 - Reuters instrument codes
524 http://www.jukkarannila.fi/lausunnot.html#nro_37
525
- 526 EN: Opinion 39: Registry options to facilitate linking of emissions trading systems
527 http://www.jukkarannila.fi/lausunnot.html#nro_39
528
- 529 EN: Opinion 40: Media Freedom and Pluralism / audiovisual regulatory bodies
530 http://www.jukkarannila.fi/lausunnot.html#nro_40
531
- 532 EN: Opinion 41: AT.39398: observations on the proposed commitments
533 http://www.jukkarannila.fi/lausunnot.html#nro_41
534
- 535 EN: Opinion 42: Opening up Education
536 http://www.jukkarannila.fi/lausunnot.html#nro_42

³ <http://www.cen.eu/> (Accessed 2 July 2012)

⁴ <http://www.acer.europa.eu/> (Accessed 2 July 2012)

537

538 EN: Opinion 43: Publication of extracts of the European register of market participants

539 http://www.jukkarannila.fi/lausunnot.html#nro_43

540 NOTE: Organised by The Agency for the Cooperation of Energy Regulators (ACER)

541

542 EN: Opinion 44: Evaluation policy guidelines

543 http://www.jukkarannila.fi/lausunnot.html#nro_44

544

545 EN: Opinion 45: About ICT standardisation

546 http://www.jukkarannila.fi/lausunnot.html#nro_45

547

548 EN: Opinion 46: Review of the EU copyright rules

549 http://www.jukkarannila.fi/lausunnot.html#nro_46

550

551 EN: Opinion 51: European Area of Skills and Qualifications

552 http://www.jukkarannila.fi/lausunnot.html#nro_51

553

554 EN: Opinion 52: Trusted Cloud Europe Survey

555 http://www.jukkarannila.fi/lausunnot.html#nro_52

556

557 EN: Opinion 53: Trade Reporting User Manual (TRUM) (Draft)

558 http://www.jukkarannila.fi/lausunnot.html#nro_53

559 NOTE: Organised by The Agency for the Cooperation of Energy Regulators (ACER)

560

561 EN: Opinion 55: European Energy Regulation

562 http://www.jukkarannila.fi/lausunnot.html#nro_55

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573 [Continues on the next page]

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577 DISCLAIMERS

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580 All opinions in this opinion paper are personal opinions and they do not represent opinions of any legal entity I am
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5 Based on the Finnish three-party system there is a phenomenon called extreme-centre in Finland. The 2011 parliamentary elections in Finland challenge the three-party system, since three "old" parties were not traditionally as the three largest parties. The is now a "new" party as the third largest party. We all must remain being interested about this new development in Finland.