

Response to WHITE PAPER

Modernising ICT Standardisation in the EU - The Way Forward

Continua Health Alliance is a non-profit, open industry coalition of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. With more than 200 member companies around the world, Continua is dedicated to establishing a system of interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals and provides the opportunity for truly personalized health and wellness management¹.

The Continua Alliance warmly welcomes the present White Paper and the invitation to comment. Continua Alliance feels that its activities are at very centre of this debate as the primary goal of the association is the development of technical design guidelines that are enabling vendors to build interoperable sensors, home networks, telehealth platforms, and health and wellness services; together with the establishment of a product certification program with a consumer - recognizable logo signifying the promise of interoperability across certified products

We would like now to comment on the specific issues raised in the White Paper.

2.1. Attributes of ICT standards associated with EU legislation and policies

(a) Continua Health Alliance agrees with the suggestion to base the standardization processes on the attributes developed in the WTO. We stress particularly the elements around consensus where every effort must be made to include trade associations and fora in the standardization processes, moreover in cases where these entities have already developed a body of work. The European standardization process shouldn't be a competitive activity, but rather collaborative and complementary.

2.2. The use of ICT standards in public procurement

(b) and (c) Continua Health Alliance supports both suggestions. With regards to CD 87/95/EEC we stress that the revision should look at the role of consortia and fora, namely in support of technical interoperability. The Commission might, in addition, consider analyzing Directive 98/34/EC in view of the results of the present consultation

2.3. Fostering synergy between ICT research, innovation and standardization

(d) The link between research and standardization activities is not trivial. These processes should happen in Parallel with one another – research completing new initiatives and standards forming a fully homogeneous approach to a problem. However, those research activities that envisage results that are closer to the market should, indeed, be well aware of relevant standardisation initiatives and vice-versa. We consider that a “one size fits all” approach does not exist and we recommend the effort should be placed on stimulating the reciprocal awareness of research and

¹ Full details may be found at www.continuaalliance.org

concomitant standardization activities. This process will allow the organisations appropriate inclusion of research while not expanding timelines.

(e) and (f) Striving for an inclusive European standardization process, would naturally allow participation of all relevant stakeholders, research entities included. A standardized approach to insertion of completed or relevant research should be formulated in standards bodies.

2.4. Intellectual property rights in ICT standards

(g) In Continua, we work to ensure an open standard for the interoperability of personal health systems which conforms with ISO and other SDOs, while allowing freedom to individual manufacturers to innovate and create intellectual property. Continua Health Alliance follows (F)RAND licensing to make its interoperability guidelines widely available. Therefore, we practice and are in favour of clear transparent and balanced IPR policies.

However, realizing that IP is a pillar for stimulating innovation in free-market programs and that a sufficient level of confidence to allow innovators to contribute to standards with their best technologies will result in companies and consumers benefiting from these technologies, we would not favour political mandates for specific IP policies.

2.5. Integration of *fora* and consortia in the ICT standardisation process

(h) Continua Health Alliance supports the principle of referencing ICT related standards and/or guidelines from specific *fora* and consortia in relevant EU legislation and policies. This is important to provide official reference to the latest established standards and guidelines stemming from consortia and *fora* meeting the criteria proposed in this White Paper. Those qualified *fora* and consortia will have spent many hours and resources evaluating specific standards. This will allow best practice implementations with the ESO's where they may have not had resources to fully evaluate specific activities.

We recognise, however, that judicious and transparent processes must be set in place to:

- identify the areas where strict regulatory compliance is involved (e.g. those directly impacting safety and health protection matters), for which the three ESOs would continue holding the exclusive responsibility;
- evaluate said standards/guidelines and *fora*, including when in presence of multiple valid alternatives;

We anticipate that the strict compliance with the ten criteria proposed in the White Paper together with sound evaluation procedures will deter the proliferation of ad-hoc initiatives lacking representativeness and causing superfluous market fragmentation.

(i) Continua Health Alliance strongly supports that better cooperation and coordination between *fora* and consortia and ESOs is needed. Moreover, the ESOs should revise their methods of collaboration and internal procedures in view to accommodate and incorporate standards and guidelines from *fora* and consortia meeting the criteria suggested in this White Paper. *Fora* and consortia outputs, once trusted and proven, should translate into a straightforward endorsement process by the ESOs.

2.6. Enhancing dialogue and partnership with stakeholders

(j) and (k) Continua Health Alliance supports both suggestions and in general of any initiative that brings true multi-stakeholder representativeness to discuss and supervise standardisation policies and activities.

Moreover, we suggest the creation of mechanisms that would allow for periodic evaluation of potential relevant *fora* and consortia as well as for independent evaluation and impact assessment of the EU standardisation process.