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Future mandates/questions for the Expert Panel on effective ways of investing in health

Fields marked with * are mandatory.

Expert Panel on effective ways of investing in health

The Expert Panel on effective ways of investing in health is an interdisciplinary and independent group established by the European Commission to provide non-binding advice on matters related to effective, accessible and resilient health systems. The Expert Panel supports DG SANTE in its efforts towards evidence-based policy-making and the development and availability of state of the art cross-country knowledge. The Panel issues opinions to inform national policy making in improving the quality and sustainability of their health systems and support EU level cooperation to improve information, expertise and the exchange of best practices.

After the appointment of the new members of the Panel by Director-General of DG SANTE in December 2019 the Panel should work on three mandates/questions in 2020. We would like to get an input from stakeholders - registered HPP members which questions the Panel should elaborate in their opinions.

* Organisation you represent

Avicenna Alliance

* What question(s) should the Panel's opinion(s) address? (You can suggest more than one)

1000 character(s) maximum

In what way could computer modelling and simulation (CM&S) be applied to allow the complete assessment of healthcare technologies by reimbursement authorities to ensure only the safest and most cost-effective treatments are funded?
How could healthcare data be made more available to researchers and industry to create new models that can help develop tailored treatments and adapt existing treatments towards individual patients?
How can existing standards such as the US V&V40 standards be adjusted and adopted into EU policy and which steps need to be taken to develop “Good Simulation Practices” for use both at EU and international level?
What are the Panel’s suggestion to ensure that CM&S clinical evidence are accepted, validated and reviewed by regulators in both medical devices and medicinal products?
Would the Panel consider that a public consultation on CM&S in health might be necessary to better understand the current regulatory barriers and to gather potential solutions?

* What is the rationale for the proposed opinion(s), how is it linked to the EU health activities?

4500 character(s) maximum

Today our very knowledge base of how to invest in health is limited due to the lack of consistent uptake in computer modelling and simulation. The ability to integrate vast quantities of raw data and turn this into actionable information must mark a significant change in how we view healthcare investments.

Reducing costs from polypharmacy

Our understanding of the interactions of multiple drugs is very limited due to the sheer complexity of these interactions. Instead of receiving multiple medicines on a trial and error basis to see what works, computer modelling and simulation can ensure that patients will receive an individualised treatment with one medicinal product at a dosage set for just that patient to ensure maximum outcome and reduced length of stay in costly healthcare institutions. Computer modelling and simulation can help to identify patients that would be receptive to certain treatments and ensure that effective medicinal products are not discarded.

Investments in a policy and physical infrastructure for computer modelling and simulation will pay off by drastically enhancing our knowledge of drug interaction.

Enhanced knowledge of effectiveness of Orphan Medicinal Products

The low numbers of patients available for trials in rare diseases is a constant challenge to manufacturers of orphan medicinal products. By investing in computer modelling and simulation and providing incentives in the Orphan Medicinal Products Regulation for its use, we can conduct virtual trials which can augment existing trials and ensure we only invest in the most promising orphan medicinal products.
Boosting SMEs

Computer modelling and simulation not only benefits healthcare stakeholders, but also enables small and medium-sized enterprises (SMEs) to be more competitive. By encouraging the use of virtual trials, SMEs can better compete with larger life science actors with greater resources to spend on traditional trials.
Better implementation of what we already have
The medical devices regulation will come into effect in 2020. An often-overlooked section of this is Article 4.5.4. “Pre-clinical evaluation assessment” which provides:

“The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address… the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, in particular of… the pre-clinical testing, for example, laboratory testing, simulated use testing, computer modelling, the use of animal models...“

This is the first instance in which computer modelling and simulated testing has formed part of the regulatory framework in medical devices legislation.

In order to reach the point where computer modelling and simulation can be relied on by regulators, standards need to be created and a body of evidence collected and validated by knowledgeable scientists to support them.

The expert panel should also reflect on the idea that to ensure better investment in health, we need to ensure that our policy frameworks are robust enough to support these investments and technological developments.

* What are the main issues to be covered by the Panel's opinion(s)?

4500 character(s) maximum

1. What should be the general role of computer modelling and simulation in healthcare today and in the foreseeable future?

2. How could computer modelling and simulation be used to better inform decisions as to which healthcare technologies should be funded?

3. What barriers currently exist to investment in computer modelling and simulation in healthcare?

4. To what extent could computer modelling and simulation can be used to address issues in polypharmacy, particularly in an ageing society?

5. To what extent could modelling and simulation help fill in gaps in our knowledge of rare diseases due to limited patient cohorts?

6. Could computer modelling and simulation makes paediatric clinical trials (quasi) obsolete in a foreseeable future?

Contact

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