Regulatory framework applicable in the field of personalised medicine

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SANCO B5: Medicines: policy, authorisation and monitoring

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STAMP Commission Expert Group
10 March 2016

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Council conclusions on personalised medicine for patients

Invitations to the Member States and the EC

- Expert group on safe and timely access of patients to medicinal products (STAMP)
- Study Big Data
- Cooperation on HTA
- Commission expert groups on cancer control and rare diseases
- European Reference Network

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Invitations to the Member States and the EC

"through the STAMP to analyse issues related to the implementation of European Union pharmaceutical legislation with the aim of ***identifying ways to maximise effective use of existing European Union regulatory tools*** *and further improve safe and timely access to medicines for patients, including innovative medicinal products; and to continue,* ***to monitor progress on the adaptive pathway pilot project*** *undertaken by the European Medicines Agency and its potential to* ***allow early authorisation of a medicine for use in a well-defined patient population with a high level of medical need"***

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Challenges along the lifecycle of a personalised medicine

- Clinical development phase
  - **Integration of data**
  - **Use of biomarkers**
  - **Clinical trials designs**

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Challenges along the lifecycle of a personalised medicine

- Marketing autorisation phase
- **Regulatory pathway, medicines and IVD laws**
- **Labelling and packaging information**
- **Post approval changes to products and monitoring**

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Questions to the STAMP

1. Is the current model of clinical development appropriate for personalised medicine? What are the specificities and the possible hurdles in the clinical development phase of such medicinal products?

2. Are there challenges for the marketing authorisation of personalised medicines? Would the move to smaller subset of diseases lead to more conditions associated with 'orphan' designation?

3. Could existing regulatory routes be used better and in what way (e.g. conditional marketing authorisation) to take into account personalised medicine?

4. Is there a need for new regulatory tools and/ or pathways (non-legislative) to support the development, authorisation and access to personalised medicine (e.g. adaptive pathway, research on the qualification/validation of biomarkers, scientific guidelines)?

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Questions to the STAMP

5. What is the interplay between the legislations on medicinal products and *in vitro* diagnostics (IVD) and what are the elements to be taken into account to allow for an optimal authorisation and use of personalised medicine? Is the availability of the IVD a matter of concern for the suitable use of the medicinal product?

6. What synergies could be created between innovators, regulators and HTA bodies, taking into account, as appropriate, input from patients, healthcare professionals and payers, to support evidence generation and regulatory authorisation and patient access to personalised medicine?

7. Are the current guidelines for defining the product information (SmPC, product leaflet) properly addressing the specificities of personalised medicine and the needs of health care professionals and patients?

8. What are the possible challenges after marketing authorisation? How could these be addressed?

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Thank you for your attention

More information:

http://ec.europa.eu/health/human-use/personalised-medicine/index_en.htm

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