EBE position on "Use of '-omics' technologies in the development of personalised medicine"

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The European Commission (EC) has recently published a report on 'Use of '-omics' technologies in the development of personalised medicine'. The report has been analysed by European Biopharmaceutical Enterprises, EBE, - the trade association representing the views of biopharmaceutical companies using biotechnology to develop innovative therapies.

Many of EBE's members are engaged in the development of personalised medicines and companion diagnostics, often utilising 'omics' technologies in the discovery of these innovative therapies. EBE considers the development of personalised medicines as an important area of scientific innovation that can bring significant benefits to both patients and healthcare systems. To ensure that the EU remains at the forefront of development of these technologies, EBE believes that the EU Institutions must continue to encourage innovation with appropriate industrial policy, regulatory provisions and a fit-for-purpose reimbursement environment.

The EC report details a number of key opportunities and challenges in basic and clinical research that will impact the development of biomarkers, companion diagnostics and personalised medicines in the EU. These include the need for:

- Increased investment in bio-informatics, data standards & data hubs
- Greater inter-disciplinary and cross-border basic and clinical research collaboration
- Implementing quality standards for bio-banks and various 'omics' platforms such as high throughput DNA sequencing
- Systems to allow collection of population health and clinical data and linkage of this data to other 'omics' datasets
- Adequate privacy safeguards, while allowing cross-border collaboration to generate the large datasets required
- New approaches to clinical trial design and analysis
- Improved education and training of health care professionals

If these challenges were successfully addressed, this would provide an enhanced platform for the discovery, validation and clinical implementation of biomarkers, which is one of the fundamental prerequisites for the development of personalised medicines and companion diagnostics.

However, having correctly identified many of the challenges facing the development of personalised medicines in Europe, the report surmises that current EU policy and regulatory efforts are adequate to address these hurdles.

EBE strongly believes that more can be done by the EC to encourage the rapid development and uptake of personalised medicines in the EU. In particular EBE see opportunities for initiatives to:

- Develop common quality and data standards for genomic information, to allow collaborative research
- Develop common quality and process standards for bio-banks and '-omics' platforms, to facilitate use of these valuable resources in collaborative research across the EU
- Develop common methods for Health Technology Assessments (HTAs), making the reimbursement process more predictable and value based
- Develop interoperable e-health record platforms across the EU, allowing generation of large clinical datasets for research
- Develop data privacy laws that protect privacy, but also allow for cross border research initiatives and linking of datasets for research
- Encourage adoption of new approaches to clinical trial design and analysis, and promote the acceptability of these approaches for regulatory submissions
- Ensure that the new In Vitro Diagnostic (IVD) Regulation includes a rigorous assessment of the clinical validity and utility of companion diagnostic tests, and that tests developed in-house meet similarly stringent quality standards
- Ensure emerging 'multi-test' diagnostic platforms (such as high throughput sequencing) have appropriate quality standards
- Foster 'adaptive' and 'fast track' licensing pathways that, based on reasonable evidence of a positive risk-benefit analysis, allow accelerated market access for high impact personalised therapies and further develop areas for incentivisation in the regulatory and reimbursement environments
- Shift to 'adaptive' and 'fast track' licensing pathways that, based on reasonable evidence that there is a positive risk-benefit analysis, allow high impact personalised therapies to reach patients more quickly with ongoing

evidence generation and safety evaluation. EBE proposes to work within the current legislation and in the framework of conditional marketing authorisation and accelerated pathways with true adaptive approach in combination with the value based aspects of HTA. Furthermore, this should include common methods for HTA assessment, making the reimbursement process more predictable and value based

"Higher level of acceptance and adaptation does not mean increasing risk. Continued measurement and evaluation need to take place at all stages of the medicines life cycle", Roberto Gradnik, President EBE.

EBE strongly believes that implementation of such initiatives by the EC would positively impact innovation in personalised medicines and could lead to a substantial increase in the quantity, quality and pace of development of these important therapies in the EU.