IMI2 JU Scientific Committee recommendations regarding equitable access

Summary

Reducing inequity in health is an important global health objective. This is also true for the European Union as based on many studies, there is a significant health gap between higher and lower income European Member States.

Unmet medical needs may not necessarily be equal across European countries, and known and unknown differences might be attributable to heterogeneity of patient populations in terms of clinical or genetic profiles or heterogeneity of patient pathways. Without doubt testing clinical hypotheses in different geographical locations is an important criterion to provide appropriate solutions for reducing the burden of diseases all across Europe and globally. When development of new technologies (including medicines, medical devices, diagnostics or complex therapies) is supported by public investments and resources of the EU, this implies that we should pay special attention to the representation of those countries where clinical sites and patient participation rates are currently underrepresented in clinical trials and, in particular, to ensure applicability of the new developments across different regions in EU funded projects.

Differences in patient access to health technologies also contribute to health inequalities. Innovative health technologies are usually targeted to markets with higher potential for uptake and deployment, which is based on an appropriate business rationale. However, if we rely on market forces, new technologies will often become available to patients in lower income countries only after many years of delay or with significant patient access restrictions [1][2]. Consequently, if patients in lower income countries have more limited access to innovative health technologies with proven significant clinical benefit than those in higher income countries, the health gap between these countries may increase. Pharmaceutical companies are not mandated to explore how to avoid unequal patient access to new technologies. However, when developments have benefited from public incentives and investment into pre-competitive research through public-private partnerships, such as IMI2, it may be warranted to consider this aspect more thoroughly by finding solutions that diminish inequities in patient access to these developments. From this point of view, the current public interventions implemented for driving medical innovation in the EU are not efficient in reducing the inequity in patient access to new technologies.

Several European collaborative health policy research initiatives (e.g. IMI2 projects ADAPT-SMART or PARADIGM) have focused on countries with quite advanced health care systems, but transferability of deliverables from these projects to less advanced health care systems was not tested. As a consequence, such projects result in improvements in the more advanced health systems but their applicability to less developed systems remains unclear, which may also enhance health inequalities.

In future programmes, the European Union needs to take into account how research projects, in particular those funded through public-private partnerships, can facilitate the reduction of health gaps between countries with different patient subgroups, economic status or advancement in health system design. Generally speaking, the health inequity can be addressed by several policy measures to be applied in public-private partnership initiatives, e.g.:

- More testing of clinical hypotheses among patients from lower income EU Member States, especially if any difference is assumed in clinical or genetic profiles (if this is not expected, this needs to be justified by data).
- Research projects that are targeting the late phase development of new technologies should include a work package about health technology assessment (HTA) and policy solutions and financing models with the aim to reduce inequity in patient access aftermarket authorisation.

- Health policy research projects should ensure appropriate coverage of countries with different economic status and advancements in health system, and the transferability of recommendations to lower income countries should be an explicit criterion in the evaluation of research proposals.

Indirectly, an increase in the participation rate of EU13 countries (which has so far had a limited participation rate in IMI project consortia), can also support the abovementioned objectives. Direct influence on how European research funds could be allocated in a more equitable way across countries can be considered a political objective, but from a research perspective participation of representative Member States might also result in higher quality standards in clinical development and broader acceptance of results across the Member States. The IMI2 Scientific Committee, therefore, recommends setting up policy measures rather than political measures.

Recommendations

In conclusion, by

1) taking into account the heterogeneity in patient populations and assessing differences in unmet medical needs in pharmaceutical R&D,
2) developing innovative concepts for equitable patient access to medical innovation across EU Member States,
3) requesting data on transferability of health policy recommendations to lower income countries with less advanced health systems

future collaborative European research initiatives, including public-private partnership for innovative health, will have the potential to reduce inequity in health in the European Union and beyond.

On behalf of the Scientific Committee

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References

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