

National Research and Development Centre for Welfare and Health STAKES

Contribution to the public hearing on Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights

Summary:

We would like to welcome the process and engagement of WHO in the difficult and multisectoral area of public health, innovation and intellectual property rights and the development of the current plan of action. We welcome, in particular, the global role of WHO in this process and emphasise the need to recognise that in a globalising world there is a need to strengthen global action in the field of health and research and development for health. Innovation is not the sole propriety of product development and we would in this context also wish to emphasise the scope and importance of innovations in regulatory measures, resource gathering and other health and social interventions. Achieving innovative products is not sufficient as such, but these need to respond to health needs, be cost-effective and provide benefits in comparison to existing products. This emphasis on health and health systems needs for innovation could also be more prominent in the Global Plan of Action. In this process we would like to highlight four core elements of importance and highlight particular issues in these fields. These issues, we believe, would be prioritising research and development, ensuring policy space for health, supporting access to medicines in the broader context of health policies and rational use of medicines and assessing and enhancing mechanisms to promote innovation that are responsive to health and health policy needs.

Prioritizing research and development

We welcome the focus of the current plan on research and development, but we are concerned that the starting point of prioritisation is already narrowly defined. We would like to remind as well of the task of the operational paragraph four in the Resolution 59.25., which emphasised the need to continue to issue public-health based reports on gaps and needs concerning pharmaceuticals. STAKES would also like to emphasise the necessity of mapping and understanding better the current global focus on research and development so as to provide appropriate reference line and anchor for estimates on global R&D. We would welcome covering not only gaps in research and development on particular diseases and/or pharmaceuticals, but as well on measures and interventions which address determinants of disease or seek other than pharmaceuticals-based remedies or solutions to crucial health problems. We would also like to emphasise that ability to guide R&D on the basis of health priorities is not an issue of concern only with developing countries as substantial and repeated concern has been put to research on antimicrobials due to problems of antimicrobial resistance. As the global knowledge-based agency in health, the WHO is the appropriate organisation to cover and implement this task. This would support the work at national level and allocation of public funding in support of research and development also within developed countries in a more informed way. Restricting basis of prioritisation process to very few diseases before the prioritisation also leads to undermining the process of prioritisation.

The focus of global action and further global support to research and development efforts needs to be prioritised. We would like to highlight that while there are widely known concerns for particular diseases and support for these, it would, from research and health policy perspective, be meaningful if the global plan of action would not define explicitly particular diseases for support, but that areas for support would be further

complemented after the prioritisation process and on the basis of gaps that are found. There has been pressure to focus on a narrow defined group of few very neglected tropical infectious diseases, but in practice focus on particular diseases is not necessarily very helpful in long-term and leads to a danger of further fragmentation and competing initiatives between different diseases and conditions operating in silos. As part of this process it could be meaningful also to consider other specific emphases than mere comparative prevalence in developing countries, such as R&D on emerging infections or putting relatively more emphasis on diseases and conditions where there is no effective treatment or where this is in danger of becoming compromised. The current emphasis on the need for global action for neglected diseases is one example of problems of focussed action as this takes place in the aftermath of global focus on HIV/AIDS, tuberculosis and malaria. It is likely that if prioritisation is merely based on defined diseases, another well deserving disease or disease group will emerge soon for another plan for global action. It is also important to put emphasis in addressing gaps in R&D with focus on developing countries needs in relation to diseases and conditions prevalent in developed countries either due to different disease prevalence across populations, age groups or different pre-conditions in health systems.

The focus on R&D and global action on gaps in R&D is not likely to cover explicitly the same diseases as measures concerning access to medicines as the latter comprises of generally broader group of diseases and thus more emphasis on non-communicable diseases than research and development activities would need to do, due to broader focus on R&D on these in developed countries.

The Global Plan of Action could include a proposal for all countries - and not only for developing countries - to develop national research plans on health and to define national priorities in health R&D on the basis of health needs and health policy priorities, including research on medicines. The global plan of action could also integrate broader global commitments made in the field of health research more clearly to the plan of action as otherwise there is a danger that current global plan of action becomes a mechanism for a separate pharmaceuticals and diagnostics oriented strategy undermining, rather than supporting and linking with other health research.

We would also emphasise the need to support the WHO role in coordination of global efforts in the field as well as support the strengthening of existing multilateral global joint mechanisms in this field, such as the Special Programme for Research and Training in Tropical Diseases (TDR). The flooding of public-private-partnerships and new initiatives has been encouraging in terms of new support, but it has also created a lack of global architecture in R&D and further fragmentation of efforts. It is also necessary to ensure that support to public private partnerships does not become mere public sponsorship. The emerging role of global charitable institutions in financing of R&D efforts is encouraging, but cannot replace global formal measures in the area as priorities of charitable institutions are decided outside formal organisations of global health governance.

Ensuring policy space for health

Globalisation and increasing integration of global economy has its repercussions to health policies and health. This is of particular importance in ensuring sufficient health policy space of governments to take action for health. Maintaining national policy space requires also support, improved action and understanding of the issues at global level. While governments are and should be able to negotiate trade agreements or design industrial policies on the basis of their national priorities, Ministries of Health would often benefit from support and analysis on issues of importance to health policy priorities, when dealing with trade negotiations or industrial policies with relevance to health so as to avoid negative repercussions and costs born by the health sector. Global support can not be done and be maintained merely in the context of technical advice upon request. Strengthening existing WHO capacities and global presence in the field would also be beneficial to global industrial and trade policies in the field so as to better enable to separate relevant health policy priorities and issues from mere industrial policy disputes between different countries.

The Global plan of Action will need to be clear also in recognising that governments will be able to use the existing TRIPS flexibilities for the benefit of public health policies without pressure or threat. In this context it is necessary to tackle also the issue that ability to use TRIPS flexibilities becomes effectively compromised if this policy space is in practice diminished through alternative means in the context of bilateral treaties or through pressure from industrial policy measures and priorities. This problem applies also more to middle-income countries and thus needs to be addressed in this context.

We would like to have more explicit recognition that governments need to have sufficient national policy space for regulatory action and measures in health and in particular, pharmaceutical policies, in order to fulfil their public health obligations and responsibilities as part of the strategy. Pharmaceutical policies are within WHO mandate and there is a need for increased focus in the field so as to ensure that governments will have scope to implement national medicine policies, including reimbursement and pricing of medicines and assessment of cost-effectiveness and clinical value of new products against existing ones. Particular attention needs to be drawn to the task of addressing ethical regulatory issues in the light of the emerging shift of clinical trials to developing countries and due to emerging role of commercial operators undertaking these, especially as a part of commercial operators will seek contracts also in marketing of the products. This aspect has become weaker in the strategy. It is also important that strengthening of regulatory oversight serves health needs. This is important with respect to addressing counterfeiting and substandard drugs, where the main concern is over substandard drugs and needs to be grounded on support to functioning and adequate regulatory capacities on quality and quality assurance of medical products.

Supporting access to medicines in a broader context of health policies and rational use of medicines

Supporting access to pharmaceuticals needs to be seen in the broader context of health policy priorities and health system functions. The strategy still considers health systems and global disease control programmes predominantly as delivery and financing channels for new health products, which leads to a problematic emphasis as well as undermining rational use of pharmaceuticals. What is urgently needed is that development efforts of new products respond more to health needs and needs of health systems. This would imply, for example, that there is sufficient reserve to cope with concerns, such as antimicrobial resistance. Furthermore, all new products are not necessary or better than existing ones, thus their use needs to be compared with existing products and in linkage with other means to tackle the same problem. We should not be blinded by enhancing access to new products merely because this would provide finance for product development, but recognise the complexity of issues in question.

It is also clear that while substantial resources are allocated in support of R&D and access to pharmaceuticals as part of development policies and global efforts, there is a lack of focus on health systems and sustaining adequate human resources. This has mounted towards concerns of medicines without doctors. There is a need to ensure as well more sustainable health systems support as part of the global strategy. However, this does not imply that access to medicines would not matter. As the share of medicines as part of national health care costs is relatively higher in developing countries, there is a specific concern over costs of medicines in the developing world. Patients in the developing world are also less likely to be able to bear costs of medicines. This is an issue which is of relevance also in middle income countries. The costs of second-line HIV/AIDS drugs have been of particular concern and remain an example where new drugs are of concern. The reality is that if there is a new effective treatment to a disease for which there is no previous treatment or one that has been compromised, it remains an issue of access globally. Global work and support in the field of essential medicines has been and remains an important part of addressing the issue, but emphasis on essential medicines in the current plan of action does not tackle broader issues and needs to be framed more in the context of health systems needs, strengthening regulatory capacities and rational use of medicines.

We would also like to emphasise the importance of further focus on pricing and scope to influence prices of medicines. WHO work on pricing has been important and has found large variation of prices between countries. The provision of information on prices of medicines is an essential part of addressing concerns with respect to monitoring supply system of pharmaceuticals. Countries must be able to use available mechanisms to address this issue as well as to ensure that competitively priced products remain in production so as to secure supply of necessary health products or adequate quality within countries. It is thus not only the new products that are of concern for access, but as well continuity of production of such good quality medicines and vaccines, which may not gain sufficient commercial interest.

Assessing and enhancing innovative mechanisms responsive to health and health policy needs

The Global Plan of Action needs to look forward and to be able to give scope for innovation also in the field of global regulatory field, financing of research and development and gathering resources in support of global measures. The global plan of action could and would benefit from serious exploration of different options for Treaties and Conventions, for example, in terms of securing sufficient support to research and development on the basis of health needs and/or in ensuring national policy space for health. The presence of legal agreements in other fields tend imply that in the absence of global standard setting and regulatory measures for health in the field, measures oriented towards and for the commercial sector, industrial policies or trade may end up defining and framing the scope for global regulatory measures also for health, with the consequence that emphasis and priorities may not adequately reflect health needs and health policy priorities at global level or within countries.

We support the emphasis on innovative approaches and the encouragement of proposals for health-needs driven research and development as part of the public consultation. It would be useful to have a full account of different proposals, in particular prize funds, which have been referred to in the document, so as to ensure that Member States are adequately informed in the IGWG. We would wish to highlight the scope for considering new and existing possible mechanisms of gathering financing for global action and support as another separate task so as to ensure further sustainability for the global plan of action. Innovation is not the sole propriety of product development and pharmaceuticals. While the current emphasis is to a large extent on innovation and product development for health and medical treatment innovation takes place through different fields and different means, including seeking global regulatory measures for health.

Finally, we would like to highlight as well the broader importance of innovation in relation to development of integrated care and integrated services delivery models as part of support to health systems development and in relation to measures concerning health systems capacity strengthening as part of the global plan of action. There is a need to consider further and take into account the broader context in which health systems operate within countries. In this sphere we would also want to draw attention to the work of the WHO European Office for integrated health care services, which hosts programmes working with health ministries across the WHO European Region.