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Submission to WHO Public Hearing on public health, innovation and intellectual property

BUKO Pharma-Kampagne welcomes the decision to create an intergovernmental working group

“Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action” (WHA 59.24)

It is an important step to declare health R&D as a public responsibility. As many reports clearly show, new ways have to be found to improve medicines and diagnostics for poor countries and poor patients.

The main objectives for the working group should be:

- Priority setting for R&D activities
- Find new ways for financing
- To ensure that products reach those who need them
- To promote further research on better strategies to prevent and resolve health problems

What issues do you feel would be most important to be considered in the plan?

Taking public responsibility:

The working group should not merely develop recommendations but concepts for binding instruments. This concepts should result in specific activities coordinated by public institutions like WHO.

New ways of R&D

Although many public R&D activities already take place, many decisions on the continuation of development processes are driven by commercial decisions. Even if about 50% of worldwide pharmaceutical R&D is covered by public funding, the final step to bring a product on the market is left to private companies. As stated by the CIPIH-report, health supply for poor countries is of very limited commercial interest. Therefore also the R&D activities in that area are mainly driven by philanthropic motivations. To ensure the accessibility of drugs and to ensure equitable pricing, R&D has to be separated from commercial decisions. As the current system of R&D is not given by natural laws but the result of political decisions, it is mainly a question of political will to develop new mechanism for promoting R&D with the focus on drugs as a public good.

Cornerstones of new mechanisms could be:

- **Public priority setting for research** - not only focused on drugs but also on other kinds of medical treatment and prevention.
- More **public activities with clinical trials**. Although this is widely seen as an assignment for pharmaceutical companies, in the last years a lot of capacity building within public institutions took place. Of course this is easier for small phase I and II trials, but conducting large phase III trials needs mainly better coordination of existing infrastructures and funding.
- **Public leadership in R&D projects**. There is a need for finding new ways of including private companies in public activities. While there is a lot of talking about private public *partnerships*, the focus should be set on a public *leadership*. Public driven R&D projects could be put out to tender where also companies could apply.
- **Support of non-profit R&D concepts**: In the last years several new forms of non-profit organisations were founded for developing new drugs. Organisations like Drugs for neglected diseases initiative (DNDI) and One World Health Institute (OWHI) cover the whole range from basic research to product development. They can be seen as a new concept: they are decentralized, coordinate activities of many different actors and cooperate with independent partners.
This new structures already show successful work. For continuation they need more public support.
- **Capacity building in poor countries**: There is already an existing infrastructure for R&D in many countries. Several international programs like INCO and EDCTP from European Commission promote creation of research partnerships between countries from the global South and the global North. This programs should be expanded under more international coordination. The WHO working group should play a leading role in enforcing this kind of networking and capacity building.
- **Equitable handling of IPR**: As the CIPIH report stated, intellectual property rights (IPR) are not the only way to promote R&D. In many cases, strict handling of IPR hinders access to medicine. The CIPIH report gives a list of 60 recommendations how the existing system could be improved. The working group should take these recommendations as a guideline for its discussion.
- **Drugs as a public good**: The concept of public goods is based on the idea that nobody should be excluded from access to an important good because of financial, social or any other reasons. Transferred to medicines this means that access to drugs may not be inhibited by high pricing. Drugs as public good means production of cheap drugs, for example by several generic competitors.
- **Financing public R&D**: If seen as public responsibility, pharmaceutical R&D needs public financing. As already a big amount of money is going into R&D, this money has to be directed in those channels developing needed and accessible drugs. Clear distinctions have to be made between non-profit R&D and direct or indirect subsidies for pharmaceutical industry.
Two different strategies should be discussed: how to direct the existing public funding and how to get new funding.
One concept as proposed by several organisations is a so called R&D treaty. Countries sign to contribute a certain amount of money to poverty related

R&D. Another proposal is the creation of a multinational fund for R&D where countries pay in and the money is spend for development of drugs as public good that will be produced as generics.

How do you see yourself or your organization contributing to the proposed plan?

BUKO Pharma-Kampagne is a public interest non-governmental organization campaigning since many years to create a system of R&D that fullfills the real health needs and brings more social justice. The organisation is cooperating internationally to create awareness for the proplems. Target audiences are politicians, the general public and scientists. BUKO Pharma-Kampagne is actively participating in the discussion on alternative models. This includes an intensive exchange with the scientists - those who develop new drugs. With its historical background, BUKO Pharma-Kampagne has the experience and scientific knowledge to combine different aspects of the discussion as health needs, social aspects, IPRs, national research structures. The organization has 25 years experience in international networking within Health Action International and several other health networks. So BUKO Pharma-Kampagne sees its role in promoting the development of new R&D structures.

Are you or your organization already implementing components of resolution WHA59.24 at the moment? what have been the outcomes?

BUKO Pharma-Kampagne is mainly pushing the discussion by analysing the existing system on its weaknesses and strengths, and bringing in new structural concepts.

What other suggestions would you have for the IGWG and WHO, as we take forward this important and challenging task?

The IGWG should involve advisors with a focus on the social determinant of medicine, like BUKO Pharma-Kampagne, Health Action International, MSF, ISDB, cptech and others.

About BUKO Pharma-Kampagne:

BUKO Pharma-Kampagne is part of the Federal Coordination Internationalism (Bundeskoordination Internationalismus BUKO), a network of 200 Third World groups in Germany. In 1980 BUKO started a campaign against irresponsible business practises of multinational pharmaceutical companies. BUKO Pharma-Kampagne fights for a access to medicine and rational use of drugs. It cooperates with doctors and pharmacists, consumer organisations and students. Furthermore, BUKO Pharma-Kampagne is in touch with groups in more than 70 countries all over the world thanks to its collaboration with the network of Health Action International (HAI).