



Socialdepartementet

Enligt remisslista

Remissbehandling av WHO-rapport om förhållandet mellan patenträttigheter och global folkhälsa*Bilaga: WHO-resolution om antagandet av en global process***Bakgrund**

Genom en global process inom WHO, som startar i december 2006, kommer medlemsstaterna att titta närmare på sambandet mellan å ena sidan immaterialrätt, forskning, utveckling och innovation och å andra sidan fattiga människors tillgång till livsavgörande läkemedel. Behandlingen kommer att ske på basis av den rapport som presenterades för WHO:s beslutande organ i maj 2006 av en oberoende kommission som under två års tid utrett frågan. Rapporten innehåller förslag och rekommendationer på hur de olika perspektiven kan förenas. Denna komplexa fråga spänner som bekant över ett flertal olika områden och faller dessutom till viss del under EU:s gemensamma lagstiftning (t.ex. vad gäller vissa handelspolitiska aspekter). Behovsdriven forskning och utveckling lyfts fram som ett nyckeltema i den globala processen, vars färdriktning beslutades genom en resolution (se bilaga).

Syftet med remissbehandlingen

Som underlag för dess hantering av frågan inom ramen för den globala processen önskar regeringskansliet erbjuda berörda myndigheter och organisationer möjlighet att inkomma med synpunkter på de olika förslag som ges av den oberoende kommissionen. Dessa förslag återfinns på sidorna 174 – 188 i rapporten. Synpunkterna skall ha inkommit i elektronisk form till registrator@social.ministry.se **senast den 3 november 2006**. Original behöver ej skickas per post.

Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

The Fifty-ninth World Health Assembly,

Recalling resolution WHA56.27, which requested the Director-General to establish terms of reference for an appropriate time-limited body to collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation and public health;

Further recalling resolutions WHA52.19, WHA53.14, WHA54.10, and WHA57.14;

Having considered the report of the Commission on Intellectual Property Rights, Innovation and Public Health;¹

Conscious of the growing burden of diseases and conditions disproportionately affecting developing countries, particularly those affecting women and children, including an upsurge in noncommunicable diseases;

Considering the need to continue to develop safe and affordable new products² for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses disproportionately affecting developing countries;

Conscious of the opportunities opened up by advances in biomedical science, and the need to harness them more effectively to develop new products, particularly in order to meet public health needs in developing countries;

Aware of the considerable progress that has been made in recent years by governments, industry, charitable foundations, and nongovernmental organizations in funding initiatives to develop new products to fight diseases affecting developing countries, and to increase access to existing ones;

Recognizing, however, that much more needs to be done in relation to the scale of avoidable suffering and mortality;

¹ Public health, innovation and intellectual property rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. April 2006.

² The word "products" hereafter should be understood to include vaccines, diagnostics and medicines.

Concerned about the need for appropriate, effective and safe health tools for patients living in resource-poor settings;

Considering the urgency of developing new products to address emerging health threats such as multidrug-resistant tuberculosis, and other infectious diseases of particular relevance to developing countries;

Aware of the need for additional funding for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries;

Recognizing the importance of, and need for, public/private partnerships devoted to the development of new essential drugs and research tools, and aware of the need for governments to set a needs-based priority agenda for health, and to provide political support and sustainable sources of funding for such initiatives;

Recognizing the importance of public and private investment in the development of new medical technologies;

Considering that a number of developing countries have been strengthening their research and development capacity in new health technologies, and that their role will be increasingly critical, and recognizing the need for continued support for research in and by developing countries;

Noting that intellectual property rights are an important incentive for the development of new health-care products;

Noting, however, that this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain;

Noting that the Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the Agreement does not and should not prevent Members from taking measures to protect public health;

Further noting that the Declaration, while reiterating commitment to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all;

Taking into account Article 7 of the TRIPS agreement that states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations";

Stressing that the Universal Declaration of Human Rights provides that "everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits" and that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author";

Concerned about the impact of high prices of medicines on access to treatment;

Aware of the need to promote new thinking on the mechanisms that support innovation;

Recognizing the importance of strengthening capacity of local public institutions and businesses in developing countries to contribute to, and participate in, research and development efforts;

Noting that the report of the Commission requests that WHO should prepare a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries,

1. WELCOMES the report of the Commission on Intellectual Property Rights, Innovation and Public Health and expresses its appreciation to the Chair, Vice-Chair and Members of the Commission for their work;

2. URGES Member States:¹

(1) to make global health and medicines a priority sector, to take determined action to emphasize priorities in research and development addressed to the needs of patients, especially those in resource-poor settings, and to harness collaborative research and development initiatives involving disease-endemic countries;

(2) to consider the recommendations of the report and to contribute actively to the development of a global strategy and plan of action, and to take an active part, working with the secretariat and international partners, in providing support for essential medical research and development;

(3) to work to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients' and clients' needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;

(4) to encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health;

(5) to ensure that the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health is included on the agendas of WHO's regional committees in 2006;

3. DECIDES:

(1) to establish, in accordance with Rule 42 of the Rules of Procedure of the World Health Assembly, an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission. Such a strategy and plan of action aims at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and

¹ Where applicable, also regional economic integration organizations.

development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area;

(2) that regional economic integration organizations constituted by sovereign States, Members of WHO, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into international legally binding regulations, may participate, in accordance with Rule 55 of the Rules of Procedure of the World Health Assembly, in the work of the intergovernmental working group referred to under paragraph (1);

(3) that the above-mentioned working group shall report to the Sixtieth World Health Assembly through the Executive Board on the progress made, giving particular attention to needs-driven research and other potential areas for early implementation action.

(4) that the working group shall submit the final global strategy and plan of action to the Sixty-first World Health Assembly through the Executive Board;

4. REQUESTS the Director-General:

(1) to convene immediately the intergovernmental working group and to allocate the necessary resources to it;

(2) to invite, as observers at the sessions of the intergovernmental working group, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who shall attend the sessions of the working group in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly;

(3) to invite experts and a limited number of concerned public and private entities to attend the sessions of the intergovernmental working group and to provide advice and expertise, as necessary, upon request of the Chair, taking into account the need to avoid conflicts of interest;

(4) to continue to issue public health-based research and development reports, identifying from a public health perspective, gaps and needs related to pharmaceuticals, and to report on them periodically;

(5) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the Commission's report, on the development of, and access to, health care products, and report thereon to the Health Assembly.

Ninth plenary meeting, 27 May 2006
A59VR/9

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Remisslista gällande rapporten om "Public Health, Innovation & Intellectual Property Rights"

2006-10-16

1. **Läkemedelsförmånsnämnden**
2. **Läkemedelsverket**
3. **Smittskyddsinstitutet**
4. **Socialstyrelsen**
5. **Statens folkhälsoinstitut**
6. **Afrikagrupperna**
7. **Apoteket**
8. **Diakonia**
9. **Forum Syd**
10. **Föreningen Svenskt Näringsliv**
11. **Karolinska institutet**
12. **Kommerskollegium**
13. **Kooperation utan gränser**
14. **Läkare utan gränser**
15. **Läkemedelsindustriföreningen**
16. **Patent- och registreringsverket**
17. **RFSU**
18. **Sida**
19. **Smittskyddsläkarföreningen**
20. **Stockholms universitet, Juridiska fakultetsnämnden**
21. **STRAMA**
22. **Svenska Föreningen för Industriellt Rättsskydd, SFIR**
23. **Svenska Industrins Patentingenjörers Förening, SIPF**
24. **Svenska Kyrkan/Lutherhjälpen**
25. **Svenska Patentombudsforeningen, SPOF**
26. **Sveriges Patentbyråers Förening, SEPAF**
27. **Sveriges Kommuner och Landsting**
28. **Vetenskapsrådet**