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Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?

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1. In the 20th century, humankind saw the most spectacular medical advances in its history. Scientific progress helped us to identify the origin of countless illnesses and to develop treatments which have significantly improved the population's state of health. The pharmaceutical industry has played an indisputable role here by investing massively in research and development for new medicines. It continues to do so and is therefore one of the key players in the health field and at the same time a very important sector of activity in many countries.

2. For a long time, questions have been raised about the possible negative effects of the interaction between the pharmaceutical industry and health sector stakeholders. This interaction may well give rise to conflicts of interest, have an influence on the knowledge and behaviour of the players involved and result in biased decisions. In its Resolution 1749 (2010) "Handling of the H1N1 pandemic: more transparency needed", the Parliamentary Assembly had expressed its concern at the risk of conflicts of interest among experts involved in sensitive health-related decisions.

3. Despite the considerable progress made in preventing and dealing with conflicts of interest, this is still today largely a matter of hit-and-miss. By means of a self-regulation policy, the pharmaceutical industry is now adopting a much more ethical approach and legislation lays down rules in this area. However, self-regulation is not binding and the implementation of legislation leaves much to be desired.

4. Research and development for new therapeutic molecules is a costly and lengthy process. In return for this investment, pharmaceutical companies benefit from an intellectual property right on the molecules they develop, protected by a patent. This innovation model has led to the discovery of thousands of medicines. However, more and more voices are now being heard arguing that this is not the optimal approach in public health matters.

5. In recent years, in spite of the increase in the number of new medicines placed on the market, there have been very few that present a real therapeutic benefit, satisfying real health needs. In addition, we have seen an upsurge in the price of medicines, allegedly justified by the cost of research and development, which nonetheless remains opaque and broadly disputed. The exorbitant price of cancer and hepatitis C treatments is of particular concern. Public health systems are faced with constant cost increases in this area, jeopardising their ability to fulfil their role.

6. In the light of these considerations, the Assembly calls on the Council of Europe member States:

6.1. with regard to the interaction between the pharmaceutical industry and the health sector players, to:

6.1.1. incorporate into the curriculum for health-care professionals specific, mandatory training to foster

awareness of the influence of pharmaceutical promotion and how to respond;

6.1.2. introduce a mandatory levy on the promotional activities of the pharmaceutical industry and use it, inter alia, to finance a public fund to be used for the independent training of health-care professionals;

6.1.3. place an obligation on pharmaceutical companies to declare their linked interests with all health sector players, to make these declarations accessible to the public, and to establish an independent authority responsible for monitoring this matter;

6.1.4. ensure absolute transparency regarding the linked interests of experts working with the health authorities and make sure that persons with a conflict of interest are excluded from sensitive decision-making processes;

6.1.5. ensure that health-related decisions, including decisions on criteria for defining illnesses and thresholds for treatment, are taken on the basis of individual and public health considerations and are not profit-driven;

6.1.6. introduce strict regulations governing the movement from a position in the public sector to one in the private sector (and vice versa), between the health authorities and the pharmaceutical industry;

6.1.7. increase the funding of patients' associations from public funds in order to avoid over-reliance on private funding.

6.2. with regard to research and development for new therapeutic molecules, to:

6.2.1. oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion;

6.2.2. adopt a stricter marketing authorisation policy, by:

6.2.2.1. introducing criteria such as added therapeutic value (in relation to existing treatments), or a "need clause", implying that a drug must also be assessed in relation to medical need;

6.2.2.2. making it mandatory to publish the results of all clinical tests relating to the medicine for which authorisation is being requested;

6.2.2.3. where appropriate, considering restricting reimbursement by the social security system to only those medicines which satisfy such criteria and requirements;

6.2.3. ensure that medicines whose effectiveness has been established remain on the market by having recourse, where necessary, to mandatory licences in return for the payment of royalties;

6.2.4. set up a public fund to finance independent research geared to unmet health needs, including in the field of rare and paediatric diseases.

Amendment 1
Tabled by Mr Jean-Yves LE DÉAUT, Mr Pierre-Yves LE BORGN', Mr René ROUQUET, Ms Marie-Christine DALLOZ, Mr Bernard FOURNIER

In the draft resolution, insert the following two paragraphs before paragraph 6.2.4: " evaluate

the quality of biosimilar medicines, derived from biotechnologies, to develop the evaluation of analytical methods, the characterisation and knowledge of medicines derived from biotechnologies, and to ensure that the effects of reference products are fully equivalent in terms of effectiveness, quality and security;" " strengthen the role of the European Directorate for the Quality of Medicine and HealthCare (EDQM) by mandating it to certify processes for the certification of biological medicines with a view to approving sites producing biosimilar medicines and by proposing to add to the International Non-Proprietary Names (INN) the place, the laboratory and the manufacturing process;"

7. The Assembly calls on member States to prohibit any agreement between pharmaceutical companies which aims to delay, for no medical justification, the marketing of generic medicines.

8. The Assembly calls on member States to impose dissuasive penalties for any illegal practices carried out by pharmaceutical companies, where appropriate by imposing fines of a given percentage of their turnover.

9. In order to ensure the viability of health systems and the accessibility of affordable and innovative medicines in the long term, the Assembly calls on the World Health Organization to put forward alternatives to the current patent-based pharmaceutical innovation model.

10. Lastly, the Assembly calls on the pharmaceutical industry, including companies and associations, to step up its efforts to increase transparency and co-operate more closely with the public authorities in the health sector.