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The Council of Europe upholds the primacy of public health interests over industry interests

Abstract

● **According to the Council of Europe, the interactions between the pharmaceutical industry and other health-sector stakeholders raise questions about their possible negative effects. These interactions are liable to create conflicts of interest, influence the knowledge and behaviour of the stakeholders involved, and result in biased decisions. In recent years, despite the increase in the number of new drugs brought to the market, only a very few offer a real therapeutic advantage and satisfy real health needs.**

● **To solve the various problems identified, the Council of Europe has proposed, in particular, that healthcare professionals should be trained to be aware of the influence of pharmaceutical promotion and that their training should be publicly funded. It has asked the World Health Organization to propose alternatives to the current patent-based model of pharmaceutical innovation.**

The Council of Europe is an organisation based in Strasbourg, which brings together representatives from 47 European countries. It mainly has an advisory role and issues recommendations to Member States (1). On 29 September 2015, its Parliamentary Assembly adopted a resolution on public health and the pharmaceutical industry (2). The resolution is presented below in its entirety. Excerpts from the report on which this resolution is based are provided in the inset p. 222 (3).

“ **1** *During 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 interaction between the pharmaceutical industry and 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* ►►

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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.*

7 *The Assembly calls on member States to prohibit any agreement between pharmaceutical companies which aims to delay, without 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".*

Parliamentary Assembly of the Council of Europe

Selected references from Prescrire's literature search.
1- "Powers of the Assembly". assembly.coe.int accessed 10 February 2016: 2 pages.
2- Parliamentary Assembly of the Council of Europe "Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?" Resolution 2071 (2015) of 29 September 2015: 2 pages.
3- Maury Pasquier L "Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?" Doc 13869, 14 September 2015: 13 pages.

Excerpts from the Council of Europe report: "Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?" (ref 3)

" *(...)*

13. *In the case of doctors, for instance, the daily presence of the industry by their side creates both links and trust. These come to be regarded as normal, even routine, and the risks that may ensue from such apparently inoffensive interaction are underestimated. Indeed, health professionals often believe that product promotion does not influence them. They have little awareness of the influence of promotional activity, which is more effective than they imagine. Health professionals commonly take the view that "promotional activity has no effect on me".*

14. *Yet the pharmaceutical industry's marketing activities result in sales because they are able to influence health professionals' decision-making process, and therefore the prescription and supply of medicines (**a**). For example, studies have shown that doctors are more likely to prescribe medicines that have been promoted to them by pharmaceutical companies, and not necessarily for the right reasons. This can at times result in the irrational prescribing of medicines, with harmful effects not only for patients, but also for the budgets of health systems which have to reimburse the cost of those medicines.*

26. *Moreover, it is absolutely essential to overcome the reluctance of health-care professionals to accept that they are indeed susceptible to promotion, right from the very start of their training. Specific training to foster greater awareness of the influence of pharmaceutical promotion and how to respond should therefore be included as a mandatory aspect of the university curriculum of health-care professionals. In addition, as far as possible, their vocational training should be financed by public funds.*

42. *First of all, it is essential for there to be transparency about the real costs of R&D to enable the public authorities to take reasoned decisions regarding medicine prices. We must therefore demand greater transparency about R&D costs, particularly with regard to public-sector funding in R&D for new medicines. Furthermore, without seeking total harmonisation, there has to be greater transparency regarding the setting of prices in each member State, bearing in mind that there are significant differences between them.*

43. *It would also be necessary to adopt a stricter marketing authorisation policy at national and European level, while leaving enough margin for second-generation medicines. Regulators could introduce a criterion such as added therapeutic value (in relation to existing treatments) or a "need clause", which implies that a drug is assessed not only from a technical and scientific viewpoint but also in relation to medical need, making it possible to take health priorities into account (**b**). The possibility might also be considered of restricting reimbursement by the social security system to only those medicines which satisfy such criteria.*
(...) ".

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a- *Practical guide "Understanding and Responding to Pharmaceutical Promotion", edited by the World Health Organization (WHO) and Health Action International (HAI).*

b- *The "need clause" was applied in Norway until its marketing authorisation legislation was harmonised with European regulations.*

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