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Discussion and conclusions

This workshop occurred at a crucial time for the future of the pharmaceutical industry, when issues such as patent, intellectual property rights, compulsory licensing, generic competition and access to cheap medicines or other related sensitive topics moved more and more to the global scene. This has moved the dialogue from the traditional industry stakeholders and industrial/health national agencies to other key players, countries such as India, Brazil or China and other stakeholders such as NGO's and International Organizations (e.g. WTO, World Bank, WHO, PAHO, ASEAN). Access (or lack of it) to affordable good quality drug therapies for diseases such as HIV is a good example of the imbalance of access to medicines for individuals in rich and poor countries: "the availability of new antiretrovirals in the United States lead to a decrease of the age-adjusted death rate by 48% from 1996 to 1997", but 95% of individuals worldwide infected with HIV live in poor countries" (cited by Reich [4] from Fauci's findings [2]).

The objective of the workshop was to discuss a number of contributions related to globalization. Even if all papers presented did not directly address the impact of globalization, they brought better understanding of the high level of interdependence between the interests of different players. A major current topic in European circles concerned with pharmaceutical policy is to facilitate the access to cheaper medicines (increased generic competition) and to prioritize the solidarity principle (between Eastern and Western Europe and from well-insured populations to populations with poor health insurance systems). This priority setting can potentially damage the development of science in the field and innovation in Europe. According to the Italian report to the European Commission [3], European countries typically become licensees (developers) while "US firms act more frequently as licensors (originators)". However "strong success stories in some European countries exist in particular in the UK, Denmark, Sweden or Ireland". The relative decline of European competitiveness and the degradation of innovative performance is highly debated in high level groups; it raises a serious challenge for this business in Europe, with a global increase of highly competitive centers other than the US around the world, such as Taiwan, India and Canada.

The question of access to cheap medicines dominates the debate on drug policies in developed countries. On the contrary, in Europe as in the US, it is also the access to high-tech products and diagnostics and paying for quality of care in an equitable way between generations. Consumer voices however remain quite limited on the European scene, in contrast to the US scene; and therefore, there is a need to bring more evidence on the impact of pharmaceutical policies in the context of globalization, not only to traditional policy-makers and decision-makers, but also to different types of communities, for instance those exposed to different levels of risks from disease.

This workshop was a platform between academics but a few industry players, a representative from an NGO (Médecins Sans Frontières), a World Bank advisor and a trade policy-maker from the European Commission were also present. We will highlight here some of the major conclusions that can be drawn from the workshop in four areas: issues on the industry dynamics, on convergence, on pharmaceutical distribution, on payment and demand.

1. Emerging paradigms in the industry dynamics

Traditional industry analysis does not really suit the analysis of the pharmaceutical and biopharmaceutical sectors. In particular, the complexity of business models represents a big challenge for researchers trying to understand trends in research productivity, economic and financial performance and the sustainability of the current industry structure. The Finnish contributors (Brannback, Renko) and the Schweizer paper in particular confirmed the emergence of new paradigms to analyze the life-science industry, where pharmaceutical and biotech firms from Western countries are now increasingly challenged by newcomers. In particular, technological paradigm shifts were discussed such as the introduction of core products based on Monoclonal Antibody Technologies (MABS) by Drug Discovery Companies (DDC) that can be used to treat diseases from cancer to cardiovascular diseases or the new organizational forms of the drug supply, with the description of agile manufacturing systems. Moreover, capabilities required for establishing competitive advantage in the field need to combine very diverse scientific knowledge from chemistry, genomics, biotechnology and therefore may require cross-sectoral policies. Life-science was also described as an hybrid domain, whose future heavily depends on successful innovation not only from pharmacy or biosciences, but also from food science. Strategic moves towards functional food and the convergence of the pharmaceutical and the food industry were in particular discussed, based on the contribution from Brannback, De Heer and Wiklund. Functional food (nutraceuticals in the US terminology) are forecasted as "25% of all food products worldwide, in the coming decade, which means a total world market of at least US Dollars 300–700 billions", according to UBIC source (Sept. 2000).

Other forms of industry organization described during the workshop were the Pharmaclusters and virtual networks, whose locations are completely changing traditional geographical boundaries. Brannback et al.'s paper presented the strengths and weaknesses of the Finnish pharmacluster. In particular, it highlighted the strong links between university and business, but also some weaknesses such as control of financial support, size, business skills and educated labor force, and marketing know-how. The case study illustrated the strategic importance of organizations such as Contract Research Organizations (CROs); Drug Discovery Companies (DDCs) and business tools companies, in addition to university and established industrial players.

2. Convergence and political divergence

Two papers in the workshop discussed concepts of convergence and divergence. The Godet and Ferrand Nagel paper analysed the convergence of standards in the European scene with the completion of the single market. It mainly referred to technical harmonization (e.g. marketing approval, rational use, and patent), demonstrated the major divergence of political systems and discussed conceptual analysis of the convergence of medicine policies in Europe. The Cruz et de la Fuente Sabate paper provided a contribution proposing a new regulatory framework of transaction cost politics, based on the New Institutional Economics (from both public interest and capture theories). It compared the regulatory structure of Spain and the USA and concluded that despite the significant divergence of the two structures in term of flexibility, the increase of flexibility in the case of the USA lead to an increase of satisfaction of patients and pharmaceutical companies; however, the two countries showed many similarities in Spanish and US regulators' mode of action.

The convergence paradigm is a major research domain, in the context of the construction of European institutions and the debate about power redistribution between European, state or regional levels. This debate is very politically sensitive and dominated by major pressure groups.

Further research could in particular investigate how an increased role of science in the policymaking process might or might not, in the context of European countries, mediate some tensions, in particular to facilitate the distribution of power between different levels. Atik, working in the American scene seems to provide such an argument. However, in Europe, decisions are strongly influenced by lobbying groups and ideologies and shared values concerning health systems models. According to Atik: "Science-based discipline creates premises for the maintenance of national prerogatives" [1]. He argues that such premises can be particularly useful in balancing the globalization of regulatory power and that science can be a way to depoliticize international dispute.

In the pharmaceutical industry, the increased influence of science in decision making usually refers to an increasing role of evidence based medicine and economic evaluation (outcome research) in policy decision-making, especially in areas like pricing and reimbursement. However, if some European countries, such as the UK, Sweden or Holland, are already very driven by evidence-based medicine, other countries are still very reluctant to introduce scientific evidence in their political decision-making process.

Moreover, European markets, especially with the enlargement process, face increasing corruption, especially in critical areas such as the Balkans or certain PECO countries and this can largely limit the possible implementation of more scientifically driven policy-making decisions. The fight against corruption in the pharmaceutical sector has become, at the eve of the 21st century, a major priority of international agencies. During the workshop, a roundtable was organized and corruption was seen as a priority for a research agenda in Europe. For instance in the area of drug safety,

corruption combined with globalization increase risks of unethical business practices or disruptions in drug supply chains (e.g. packaging).

3. Distribution and demand issues

Two papers presented during the workshop addressed pharmaceutical marketing issues. The Chansarkar paper discussed the interplay between prescription charge policy and pharmacists' role in the UK context. Even if the methodology did not provide clear scientific evidence, it presented some arguments on potential forms of collusion between the pharmacy profession and government for non-exempted patients. This lead in particular to changes in the respective roles of physicians and pharmacists, towards a transfer of responsibility from GPs to pharmacists, for a certain range of illnesses. The increase of the prescription charge facilitates the switch to OTC medications and this deregulation of the market can favor pharmacists interests.

The relevant shortage of physicians can explain in the UK the increased role of other providers such as pharmacists and nurses. However, if further research can confirm the preliminary findings from the paper presented during the workshop, it might lead to an increased fragmentation of health care providers and a reduced legitimacy of their representative bodies.

A second contribution from industry from Harms et al, provided an example of how innovation cost dramatically increased, in the case of some new drugs launched on reduced segments of the German market, with faster duplication of knowledge, very high marketing cost with traditional communication strategy towards physicians. These industry contributors present the start of the 21st century as a "time of upheaval for pharmaceutical marketing" with in particular, shifts of innovation locus towards innovative marketing. They introduce the New 3 P's of marketing and Direct to Consumer (DTC): Positioning, Politics, and Patients, to replace the traditional 4 P's used in marketing. During the workshop, it was emphasized that companies need to propose constructive solutions. If the first P, positioning is already well covered by traditional marketing management, the two other P's were largely discussed during the workshop. Companies' representatives, present at the workshop, agreed that they had to integrate the changing political scene and offer new product understanding, including social and political plans. The direct approach to patients was also discussed. Direct to consumer advertising is very controversial, especially in the area of health care and pharmaceuticals. However, most participants agreed that in different ways, patients and citizens need to be made more aware of limited resources and of reasonable use of health care services. This would also to ensure that the issue of health services is for the best patient interest (and not only for very influential pressure groups at a certain state of medical knowledge). The workshop also concentrated on the issue of how to implement 'three P's' marketing strategies. Companies made a number of proposals, which lead to a brainstorming exchange with academics during

the workshop. The following ideas were then suggested: more innovation on market research, better management control of complexity, advanced forms of partnerships for problem-solving in different areas of health care, more education, more sophisticated communication strategies required by changing health care systems and a changing environment. The complexity control in particular raised serious concern, especially from industry stakeholders. For instance, in order to reduce and better control complexity, there is a trend towards more centralization (e.g. configuration of R&D centers and their relocation closer to headquarters). Innovation needs to be measured and managed. Such moves may limit productivity or efficiency of research and risk-taking behaviors from big players in the pharmaceutical industry. This may lead to a strong desire to reduce uncertainty. On the other hand, more and more major monopsonistic governmental agencies in Europe request value for money, but with stronger budget constraints, fostered by monetary union rules. Certain categories of patients are increasingly empowered with access to very reliable sources of information on the state of medical knowledge in the world, and they are challenging the power of health care professionals and traditional classifications of health care services.

4. Reimbursement systems and patients' perspective

The final research theme for the workshop concerned payment for medicines in Europe and patients' perspective. Pricing and reimbursement has always been a very sensitive topic for Western European countries and numerous regulations and cost containment measures exist to regulate drug systems. The two papers aimed to address some specific tools targeted at patients.

The first paper by Huttin was a preliminary report based on French findings from the European Biomed/ENDEP project on prescription charges and patient decision making. Cost shifting is a major cost containment strategy used in France. This strategy is not especially visible to French consumers, since supplementary voluntary or private insurers usually top up the proportion covered by the national sickness funds for drug coverage. Moreover, insurers are usually 'blind' payers and have so far mainly followed the policy orientations decided by the Ministry of Health. However, the gradual decrease of public sickness funding mainly in the coverage of some primary care services (such as physicians, some medicines and dental care) has increased the pressure on supplemental insurers. Some of them have responded by increases of premiums and some patient face affordability issues in this traditionally well-protected population. The paper presented the findings of patients' focus groups run in France. This method was used to explore whether and how cost of medicines, and especially copayment, influence patients' behaviors. It showed that drug choices were affected mainly with respect to timing of prescriptions, number of packs and ways to pay drugs (liquidity issues). However, the impact of cost on drug choices appears quite limited and mainly affects choice of providers in the case of an acute

condition such as hay fever. In contrast to other European countries involved in the project, the key trade-off choices were more between regularly paying 'out of pocket' for medications versus paying additional insurance premiums. Price and drug coverage were quite well known by patients with chronic conditions such as hypertension but only known by cost conscious patients in the case of hay fever. Such focus groups findings were used to design patient surveys in six countries. The main findings of these surveys will be provided in the ENDEP book (under preparation, from IOS press).

Costa and Mossialos brought an important contribution, in their paper on the current changes affecting life science and public opinion's risk perceptions of scientific progress. They identified a widening gap in Europe between science discovery and people's knowledge. The paper is mainly based on the European barometer surveys conducted on 16000 people in 15 European Union Member States. The surveys mainly cover products artificially modified by science (such as GMO's). The authors compare results from the 1996 and 1999 surveys to analyze potential shifts in risk perceptions. They showed a significant reduction in Europe in the public acceptance for biotechnology.

Such reduction could be taken as a warning against potential misuse of science, since the postwar period in Europe and the trauma from Eugenism have slowed down research and interest for genetically modified organisms. This is quite different from the North American scene, which is much more driven by science not only within the business, financial and academic communities but also within several consumer groups who are very informed about the development of sciences.

The series of appendices provided with this special issue also complements the inputs and discussions from this workshop, which was particularly important at a crucial time of reshuffling different powers on the global scene. In particular appendix 4 summarizes the main points from a roundtable, which took place for the first time during this series of workshops, in order to set priorities for a research agenda. Appendix 3 provides a summary of the contribution of the Trade department of the European Commission, updated with recent positions on major trade issues concerning the biopharmaceutical industry.

References

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