Opinion of the European Economic and Social Committee on 'Industrial Changes in the European Pharmaceutical Sector'

(2014/C 311/04)

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On 19 September 2013 the European Economic and Social Committee, acting under Rule 29(2) of its Rules of Procedure, decided to draw up an own-initiative opinion on the

Industrial Changes in the European Pharmaceutical Sector.

The Consultative Commission on Industrial Change (CCMI), which was responsible for preparing the Committee's work on the subject, adopted its opinion on 8 April 2014.

At its 498nd plenary session, held on 29 and 30 April 2014(meeting of 29 April), the European Economic and Social Committee adopted the following opinion by 195 votes to 4 with 12 abstentions.

1. **Conclusions and recommendations**

1.1 The pharmaceutical sector is one of the most important and strategic for Europe's future. Europe has a rich heritage as one of the main global hubs for pharmaceutical innovation and it has many of the pre-conditions for on-going success. Future success, though, is contingent on the policy environment supporting appropriate use of innovation in European healthcare systems.

1.2 Not only does the pharmaceutical industry have the highest value added per worker, highest research and development intensity and largest trade surplus of all high-tech sectors, it uniquely offers a broader contribution to economic growth through its products contributing to a healthy population. The sector is made up not only of large companies employing large numbers of people, but also small and medium-sized enterprises, whose margins often differ according to firm size. Its partnerships with universities and other institutions around the globe form an integrated life sciences 'system'.

1.3 In the face of intensifying global competition the Committee believes that now is right time to call for a new European Life Sciences Strategy that can ensure a more joined up approach to the industry ensuring that all stakeholder groups continue to benefit from this unique sector.

1.4 The Committee recommends that a new Life Sciences Strategy should have three elements:

— societal policy recommendations — focusing on the sector's contribution to meeting an ageing Europe's challenges of chronic disease management, as well as the need to reduce healthcare inequality;

— scientific policy recommendations — where serious effort should be given to developing a better coordinated, more strategic, pan-European research effort; and

— **economic policy recommendations**, where there is more explicit recognition that investment in healthcare, including in medicines, matters for all segments of society. The Committee recommends that all Member States work with the industry on agreements that could ensure all European consumers (i.e. patients) get equal access to modern medicine.

1.5 The role and independence of the European Medicines Agency (EMA) should be reinforced.

1.6 Europe should look to strengthen and consolidate its position as a global leader in pharmaceuticals, through partnerships that stretch beyond its own borders.

1.7 Efforts should be made to reduce inequality in access to medicines across Europe.

1.8 In terms of scientific policy recommendations, Europe should continue to pursue its coordinated strategy for medical and bioscience research in Europe, and an increased focus on excellence in basic biomedical research and education and training to achieve scientific leadership in support of the Europe2020 strategy and to foster competitiveness on a global level.

1.9 The Commission should include intellectual property as part of its forthcoming Communication on Industrial Policy for the Pharmaceutical Industry.

1.10 The pharmaceutical sector contributes to the Europe 2020 strategy, which is focused on delivering growth that is smart, sustainable, and inclusive; with a strong emphasis on quality job creation and poverty reduction. This will be achieved through more effective investments in education, research and innovation, in demand-side policies creating a 'pull' for innovative products and services and in fostering a high-quality employment economy delivering social and territorial cohesion.

1.11 These initiatives must be supported by an effective social sector dialogue and a multi-stakeholder approach.

1.12 The Committee urges the Commission to act without delay to put in place a strategy for the pharmaceutical sector in order to secure a thriving pharmaceutical industry in Europe along the entire value chain (research and development, manufacturing, sales and distribution)..

2. **Historic view and status quo of the pharmaceutical industry**

2.1 The European-based pharmaceutical industry makes a major contribution to the European Union, not just in economic terms but also in terms of high-quality employment, investment in the science base and in terms of public health. Europe has made huge strides in improving life expectancy and health outcomes over the last 60 years. The use of innovative medicines has played a major role to these recent advances. Europe is now faced with a new set of challenges.

2.2 Inequalities in access to healthcare persist and the impact of chronic conditions and degenerative diseases are resulting in more people living longer with some form of medical disability or illness. This negatively impacts on healthcare costs and productivity.

2.3 Ensuring a safe and effective supply chain for pharmaceutical products for European consumers is an important priority. The European regulatory framework, in theory, ensures that the same standards of quality are delivered to patients irrespective of where the medicine was manufactured. Nevertheless further improving supply chain security — and removing the risk of counterfeit products — through the implementation of the Falsified Medicines Directive will be an important milestone, with the coding and serialisation of every pack of medicines in Europe, which will improve traceability, an essential element.

2.4 The European Medicines Agency (EMA) was set up in 1995, roughly parallel to the US Food and Drug Administration (FDA) but without FDA-style centralisation. The EMA was funded by the EU and the pharmaceutical sector, as well as indirect subsidy from Member States, in an attempt to harmonise (but not replace) the work of existing national medicine regulatory bodies, which continue to work in a network with the EMA.

3. **Industrial changes in the pharmaceutical sector**

3.1 On average it takes over 12 years to develop a new medicine to the standards of quality, efficacy and safety expected by regulators. For every medicine that makes enough money to pay for its development, about 25 000 chemical compounds were tested, on average 25 of these will have gone into clinical trials and five will have received a licence. 'Attrition' is an inherent part of the innovation process. Given the high-risk and enormous upfront investment made by private sector pharmaceutical companies, the technologies embedded in medicines are offered a certain amount of temporary market exclusivity, for example through patents.

3.2 Pharmaceutical innovations are inspired by new science, especially in the understanding of biology. Advances in genomics, proteomics, nanotechnology and the discovery of more accurate biomarkers offer great potential to further improve the medicines available to physicians. The pharmaceutical sector is undergoing structural change driven by: the move away from primary care block-busters towards more speciality products; an increase in generic competition and ongoing R&D productivity challenges. There is also an ongoing challenge of maintaining R&D spending against a backdrop of pressure to deliver short term value to shareholders.

3.3 The sector directly employs 700 000 people (70 % of whom are women) of various scientific and technological specialities, and generates three to four times more employment indirectly. It is a high-quality employer. Its employees are well-educated and the sector generates more value-added per worker than any other high-tech sector. Compared to other sectors, pharmaceutical companies are more resilient to the short-term boom and bust cycle of the macro-economy. This is an important strength for Europe.

3.4 The medicines life cycle is an elegant framework for ensuring the ongoing flow of new useful technologies, whilst ensuring reasonable budget sustainability. One can consider three phases:

1) **R&D** — where the private sector companies take on risk in order to bring new medicines to market

2) **The on-patent market** — for companies to recoup the cost of investment, it is important that healthcare systems use new technologies appropriately and that they pay appropriate prices that reflect the value of the medicine and the affordability of the given healthcare system

3) **The off-patent market (generics and biosimilars)** — where, as market exclusivity for medicines expires, competitor products generate price erosion and therefore savings for healthcare systems that can be used to fund newer medicines.

3.5 In recent years the integrity of this 'life cycle' has come under pressure. The R&D phase has become longer, more costly and higher risk. Requirements by not just regulators but also payers within healthcare systems for more data have meant that pharmaceutical companies are obliged to spend longer doing more trials against more comparator therapies than was the case previously. During the on-patent market phase, payers have become more sophisticated and discriminating, requiring an ever-higher burden of proof on not just safety and efficacy but also on cost-effectiveness.

3.6 New science is offering the potential to better target new therapies to patients with particular characteristics.

3.7 The size of the market on which pharmaceutical companies are able to recoup their costs, is smaller than it was in previous generations whilst the costs of development have increased and are still increasing.

3.8 Finally, governments — rightly — have sought to maximise the economic efficiency of off-patent markets. Price competition that delivers a lower cost of treatment with older medicines is an important way in which governments can manage their budgets. An appropriate balance needs to be struck, however.

3.9 Whilst it is reasonable to expect rational use of older medicines, it is critical that newer and innovative medicines are used. There is substantial variation in patients' access to innovative therapies across Europe. This not only means that many patients will not get access to the best treatment; it also undermines the viability of the industry in Europe.

3.10 The European Commission estimates that the number of the population aged 65 or older in Europe will increase by 75 % by 2050. This means the ratio of people in work paying for the welfare — healthcare and pensions — of the retired will be more challenging. To reduce the burden on workers it is important that as much of the working age population as possible is fit and healthy enough.

3.11 Good healthcare can drive three important benefits: bringing some individuals who are currently not working at all into work; reduce absenteeism in the work place; and, finally, it can help with the so-called issue of 'presenteeism', whereby workers who may be suffering from some sort of illness or disability (but are still working) may be more productive with better healthcare.

3.12 Pharmaceuticals is the leading high-technology sector in terms of trade surplus (amounting EUR 48,3 billion in 2011) and it has the highest ratio of R&D investment to net sales. Its members stand for 19,1 % of total worldwide business R&D expenditure. Private sector companies spend around USD 100 billion per year on research and development, with around EUR 30 billion in Europe. The bulk of this expense is in clinical trials, which include not only trials but also post-marketing studies which are required even after a product is on the market.

3.13 Many European patients are currently not seeing the benefits of new medicines. As a consequence, not only is European health and productivity held back but Europe is also not meeting its potential to drive economic value. In a new study published by IMSHealth for a healthcare conference held by the Lithuanian Presidency of the EU, new data are presented that show the variation in access to medicines across the Union. It is consumers in the poorer countries that lose out most.

3.14 To remedy this situation the EU must create a policy environment whereby the new treatments can be priced in line with countries ability to pay as well as their demand. Medicines are unlike any other good in as far as society expects all patients to get access to the medicines they need. An active reflection by European policymakers is called for to ensure that the European single market works in the best interests of all European citizens.

Expenditure on medicines is being artificially 'capped', leading to reduced health outcomes. In countries that significantly reduced medicines expenditure as a result of the financial crisis, or shifted the financial burden from a third-party payer to individuals, health outcomes deteriorated immediately and other, more expensive forms of healthcare delivery saw increased volumes to compensate for poor access to medicines.

4. **Towards a new life sciences strategy for Europe**

4.1 While Europe holds many of the prerequisites for sustainable growth the reality is that it is losing ground to the USA as a leader in biopharmaceutical research.

4.2 The global pharmaceutical industry is mostly concentrated in the EU and the US and can help address issues of equity allowing both blocs to protect their historic and future investment in medicines. For this purpose it is important that both the economic and the social dimensions, as well as the consumer concerns, must be appropriately factored into the ongoing TTIP (Transatlantic Trade and Investment partnership) discussions.

4.3 As middle-income countries improve their prosperity, they should pay their fair share of the costs of innovation in this growing, global, market. Not only is this not currently occurring, there is a growing trend for countries such as India to enact compulsory licensing, alongside other similar strategies such as excessive pricing pressure in Korea. To address and benefit from future challenges and opportunities, we have built our conclusions on three main perspectives — social, scientific and economic, with associated recommendations in each case.

4.4 In terms of societal policy recommendations, the focus must lie on improving health outcomes for the European population in light of the demographic change and challenges due to chronic diseases. Health is a precondition for economic prosperity.

Huge inequalities persist across Europe, both between and within countries. If this is not corrected urgently the situation will get worse as our population ages.

4.5 Better medicines usage and medicines innovation can play a key role in helping Europe address these challenges. Early diagnosis, best practice pathway management and improving patient adherence are critical challenges where the industry and healthcare providers can work in partnership to improve outcomes. Serious consideration should be given to creating an environment where industry can price based on countries' ability to pay, without risking supply chain diversions.

4.6 Better use should be made of EU structural funding to support improvements in the quality of healthcare infrastructure.

4.7 European governments should target for the establishment of a European framework to evaluate chronic disease management programmes by defining benchmarks and 'best-in-class patient pathways' for holistic care, and the appropriate usage of both low cost medicines and innovative medicines in the pathway. By building up a platform for large organisational partnerships to develop secondary prevention programmes for chronic diseases, multiple stakeholders, like governments, patient and physician associations, social partners and other civil society institutions, can contribute to a successful implementation of chronic disease management. In this regard the Commission's Joint Action on Chronic Disease is an important step in the right direction.

4.8 The organisation, governance and funding of basic biomedical research across Europe is currently being managed through a range of independent and fragmented programmes at both Member State and European levels. Despite some excellent European initiatives, reality is that there is too much competition between Member States and not enough effort devoted to achieving a coherent strategy for Europe. This results in different quality assessment criteria, duplication of efforts, waste of financial resources, Europe is falling behind the US in many areas of bio-medical research leading to loss of competitiveness.

4.9 Strengthening basic and translational research, and creating world-class centres of excellence in Europe, is vital to ensure that Europe remains attractive for R&D and manufacturing investors. As Europe has consistently missed the 3 % of GDP invested into its R&D target, a renewed focus on basic science and education is required. Initiatives like the Innovative Medicines Initiative and Horizon 2020 can help drive a culture of open innovation and collaboration, and create a funding vehicle to stimulate targeted investments.

4.10 In terms of economic policy recommendations, EU should foster the introduction of a 'growth and stability framework' in the life science system across Europe to improve stability and predictability for all. The purpose of such a framework, supported by sector-social dialogue, would be to encourage the uptake of valuable new innovations, whilst safeguarding governments' ability to manage budgets in a predictable way. A framework like this would be implemented at Member State level to take into account differences in demographic development, real demand, inflation, technological advancements etc. The social dimension should also be included.

4.11 In most countries, medicines have carried a disproportionate burden of the savings within the fiscal consolidation programmes, despite their value having been proven with evidence beyond other areas of healthcare spending. This creates an unpredictable environment for industry, a confusing signal about Europe's commitment to innovation, and potentially risks Member States' ability to drive further efficiency in healthcare through the appropriate use of medicines and other technologies.

4.12 Supporting a sustainable approach to funding healthcare is a key topic for European economic stakeholders and especially consumers. The development of a more sustainable approach to medicines expenditure can ensure that funding goes to areas that provide the greatest returns. It is important to identify opportunities for improved medicines management. A minimum threshold level of financing of healthcare and medicines should be guaranteed for health in all European Member States.

4.13 This should also include realistic expectations about growth, driven by an ageing population, real innovation and long-term healthcare cost-effectiveness considerations. A framework like this would mitigate the damaging fluctuations observed in healthcare financing during the last three to five years and cultivate long-term planning for all parties involved in the healthcare system.

4.14 Through the Commission's recent Tajani initiative, important work has progressed and been achieved in terms of ethics and transparency; access to medicines, orphan drugs and non-prescription medicines in small countries; biosimilar medicines and managed entry agreements which the Committee supports.

4.15 The EESC understands that the Commission is planning an important new Communication on Industrial Policy for the Pharmaceutical Industry. This is timely and the Committee encourages it to set an ambitious agenda that secures a thriving pharmaceutical industry in Europe along the entire value chain (research and development, manufacturing, sales and distribution).

Brussels, 29 April 2014.

The President
of the European Economic and Social Committee
Henri MALOSSE