EUROPEAN SOCIETY OF ONCOLOGY PHARMACY

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Comments on Pharma Strategy from the European Society of Oncology Pharmacy

We would like to thank the European Union for this initiative, which states the major issues and challenges that we, as practicing pharmacists, are confronted with on a daily basis, and which present major threats to our patients.

In order to enable achievement of the objectives stated in the Pharma Strategy, please allow the pharmacists from ESOP (European Society of Oncology Pharmacy) to offer the following suggestions, listed per objective:

Objective 1: ensure greater access and availability of pharmaceuticals to patients

- For essential drugs, redundancy in global production sites should be implemented, not only for the end product but importantly also for the active pharmaceutical ingredients. For European citizens, dependency on outside markets poses a threat. Pharmaceutical industries that sell in Europe, should also produce in Europe.
- When health systems or hospitals issue tenders for supply of a generic medicine, requirements must ensure that at the end of the contracting process there are not less than 2 different manufacturers to provide supply, and that those manufacturers can actually guarantee the supply. This would go a long way in reducing the occurrence of generic medicine shortage.
- Manufacturers must openly report likely supply disruptions at the earliest point that a production and supply issue becomes evident. This is not occurring consistently across Europe to any meaningful extent and means that mitigating actions a health system might take to reduce the impact of the shortage cannot be taken in a timely manner. Existing EU legislative obligations (e.g. Directive 2001/83/E) could be strengthened in that regard.

Objective 2: ensure affordability of medicines for patients and health-systems financial and fiscal sustainability

- Enforce a transparent system so that authorities, patients and health-care workers can review how the price of a drug has been established
- Implement a European central procedure for granting market authorizations only if an acceptable price has been agreed upon between manufacturer and the European health

authorities. Such a scheme is already in place in some countries (e.g. France) but has not been pursued on a European level.

- Actively stimulate compounding of expensive drugs by pharmacists, for example in the case of orphan drugs or cell therapies. Pharmacists can often perform small-scale production for their own patients at much lower costs than are asked in the commercial market.
- Develop strategies to enable early identification of patients that will actually benefit from treatment with an expensive drug, by use of innovative diagnostic tools and biomarkers. For example, immunotherapy in cancer treatment has undisputable provided a breakthrough for several types of disease. However, we also know that in most cases, only 10-15 % of patients benefit from this type of treatment. The other 85-90% will not experience a response, but are exposed to potentially severe side-effects. If we can identify which patients fall into the 10-15% group, we not only save large amounts of money, but we also reduce the environmental footprint of these treatments and we prevent our patients from receiving drugs that may only cause them harm.
- Use real world outcome data through non-commercial registries for proper evaluation of drug efficacy and safety, taking into account the outcomes that are relevant for patients. These data should be made publicly available. This will enable quantification of the actual cost-benefit of expensive drugs in real world populations. These should be implemented with the help of academia and the health-care work force, from existing clinical data sources so as to not unnecessarily pose extra administrative burden to doctors, nurses and pharmacists. Examples of such registries are available in some countries (e.g. Denmark and Sweden) but have not been promoted on a European level.

<u>Objective 3: enable innovation including for unmet medical needs in a way that harnesses the benefits of digital and emerging science and technology and reduces the environmental footprint</u>

- The manufacturers should be asked by the EMA to run stability tests enabling the prolongation of shelf life of major drugs, not only for the drug product itself, but also after reconstitution. These stability data should be included in the SmPC, which will have an enormous effect on reducing the unnecessary waste through disposal of drugs that have past their shelf-life stated by the manufacturer, but are in fact still stable and good for administration.

<u>Objective 4: support EU competitiveness on the global level, reduce direct dependence on manufacturing in non-EU countries, seek a level playing field for EU operators</u>

- When there is a drug shortage in one country, often other countries in Europe still have stock. However, in contrast to the free transport of goods and people usually in force in the European Union, when pharmacists want to procure drugs in a neighboring country, they are faced with major administrative and legal hurdles causing large delays in actually securing the drug that has a shortage. A simple and effective scheme to centrally organize redistribution of drugs that are in short supply across borders, should be put in place.

We also propose a fifth objective: defining the list of essential drugs that are necessary for the EU patients.

We are willing and able to provide support for the European Parliaments' endeavors to achieve the objectives stated in the pharmaceutical strategy, which we support fully. We are at the disposal of the European Parliament to provide further explanation of the solutions we propose and to collaborate in implementation of the strategy. Please do not hesitate to contact us at any time.

With kind regards

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