22 October 2013

Dr Patrizia Tosetti
Policy Officer (Pharmaceuticals)
DG SANCO
European Commission
101 Rue Froissart
Brussels 1040
Belgium

Dear Dr Tosseti,

Resolving Europe's medicines shortage crisis: the potential leadership role of the European Commission

Our organisations would like to thank you for the opportunity to meet on Wednesday 23rd October to discuss the evidence of Europe's medicines shortage crisis, and explore with you some of the options for improving the situation, and where we consider the European Commission has a role within that.

The evidence

As you will have been made aware at the recent European Medicines Agency workshop on the topic of medicines shortages, the evidence from various quarters of the growing problem of shortages continues to accumulate.

Responding to increasing concern from members about the problem, the European Association of Hospital Pharmacists (EAHP) conducted a survey in 2012-13 to better understand the scale and nature of the medicines shortage problem from the European hospital pharmacy perspective. With over 300 responses from 25 countries, the results were stark:

- 99% of hospital pharmacists across Europe are experiencing problems with medicines shortages;
- 63% say the problem is a weekly, sometimes daily occurrence; and,
- 77% say the problem has become worse in the last year.

The Pharmaceutical Group of the European Union (PGEU), representing community pharmacy in Europe, also surveyed their membership. The survey discovered that although some countries are more affected than others, medicine shortages have been reported by all respondents to the survey and the problem is increasing. According to the survey, a broad range of medicines is affected, including even basic medication such as aspirin.

The impact for patients

Patients are at risk of suffering deterioration in their health status if they do not receive the medicine they are prescribed in a timely manner, and can ultimately suffer from serious harm that is avoidable.

For patients, shortages often translate into lower quality and safety of care, and unnecessary distress. They also reduce the amount of time various categories of healthcare professionals are able to spend with patients as they are being redeployed out of necessity to manage the shortage. Medicine shortages can trigger delays or discontinuation of both essential and recommended medical procedures and treatments, encourage the omission of medicine doses, increase the risk of surgical interventions and/or

operating times and negatively impact on patient recovery periods (shortages of anaesthetics). EAHP's survey of hospital pharmacists found many reports of chemotherapy treatments needing to be delayed or interrupted as a result of shortages

The mandate of the European Commission on this matter

Our organisations consider that the mandate of the European Commission to assist in alleviating medicines shortage problems includes, but also goes beyond, facilitating best practice-sharing. Many of the cited causational factors go beyond the abilities of member states alone to remedy, and have international, cross-Governmental aspects, including:

- the impacts of national pricing and reimbursement activities on supply sustainability across Europe;
- unintended impacts of existing European legislation such as the Falsified Medicines Directive and GMP regulations;
- globalisation of the pharmaceutical supply chain and potential risks in relation to increased vulnerability;
- the extent to which international parallel trade of medicines could be a factor (positive and negative) in some shortage scenarios; and
- emergency austerity measures associated with Eurozone countries undergoing programmes of international assistance with their sovereign debt obligations.

Furthermore, whilst health is still mainly a Member States' (MSs) competency, it is understood that the European Union should: take into account the protection of human health when defining and implementing all its policies and activities (articles 9 and 168 of the Treaty on the Functioning of the European Union – TFEU); has a shared competence with MSs when common safety concerns in public health matters occur (article 4 TFUE): and, has the competence to carry out actions to support, coordinate or supplement the actions of MSs for the protection and the improvement of human health (article 6 TFUE). In the case of tackling the urgent public health issue of pan-European medicines shortages, we believe the criteria of article 4 and 6 TFUE are met.

In summary, our organisations request the European Commission take a leadership role in steering EU Member Countries through the complexities of the problem and navigating the European community towards a more sustainable and reliable medicines supply scenario for the benefit of patient care, health outcomes and efficient health systems.

Below we make some suggestions as to what these leadership roles might include.

Requests for action by EAHP, PGEU and EIPG

Our organisations request the European Commission:

1. **PROVIDE LEADERSHIP ON BEHALF OF NATIONAL GOVERNMENTS IN INVESTIGATING THE PAN-EUROPEAN NATURE, CAUSES AND POTENTIAL SOLUTIONS TO THE MEDICINES SHORTAGES CRISIS**

Whilst the independently undertaken research of organisations such as EAHP and PGEU has been useful, illustrative and increased understanding, there are limits to what the resources of such membership organisations can conduct in terms of truly robust research. Referring to the pan-European aspects of the shortages problem mentioned above, the Commission is well placed to lead efforts to truly understand the principal causational factors of shortages in Europe, and what policy actions and options exist to combat them.

2. **TACKLE THE '*RESPONSIBILITY GAP*' IN REGARDS TO WHO HAS RESPONSIBILITY FOR ENSURING SUSTAINABLE AND RELIABLE SUPPLY OF MEDICINES BY PROVIDING THE EUROPEAN MEDICINES AGENCY WITH ADDITIONAL REGULATORY COMPETENCE**

There appears to our organisations to be an uncertainty around the issue of who exactly has responsibility for assuring and ensuring the sustainable and efficient supply of medicines to the patient in need. From our perspective this constitutes a causational factor as opportunities for action are being missed.

We note, for example, that in the USA this responsibility gap has recently been addressed in large part via the 2012 FDASIA regulation which granted additional powers and responsibilities to the FDA to take action on shortages. Some evidence exists from the University of Utah's monitoring of shortages, that use of these new powers is helping to reduce the number of reported new shortages.

We believe an honest debate should be commenced as to whether, in view of the scale, impact and reported increase in the number of medicines shortages, the competencies and powers of the European Medicines Agency should be reviewed, and consideration given to increasing their mandate in the area of shortages, for example, conducting an annual report on the situation with accompanying recommendations; greater enforcement options in terms of the obligations of manufacturers to give early notification of supply difficulties in order that timely contingency measures can be made.

3. INITIATE INTERNATIONAL GOVERNMENTAL DIALOGUE IN RELATION TO THE GLOBAL ASPECTS OF THE SHORTAGE PROBLEMS, INCLUDING SUPPLY CHAIN VULNERABILITY, UNINTENDED INTERNATIONAL IMPACTS FROM NATIONAL LEVEL PRICING STRATEGIES, AND CROSS-BORDER MEDICINES TRADE

The European Commission is well placed to facilitate greater Government-to-Government discussion on this neglected topic. The issues are not simple and no single silver bullet exists to resolve all the known difficulties. However the sooner concentrated dialogue between European countries on the topic commences, the sooner the process of solution-identification and enactment can complete.

4. CONSTRUCT A COMMISSION LED JOINT ACTION WITH THE TASK OF ENSURING USEFUL EXCHANGE OF EXPERIENCE AND MAKING RECOMMENDATIONS ON NATIONAL LEVEL BEST PRACTICES

We acknowledge the role of the Commission in best practice sharing. However we are not currently aware of any major initiatives by the Commission in this area in relation to medicines shortages. Our organisations possess anecdotal knowledge of what is working well and less well in different countries but consider that a robust process of practice assessment and information sharing is required which the Commission is uniquely placed to deliver.

We look forward to discussing these options for action with you at our meeting, and what should be a useful exchange of views, experiences and ideas on the policy options.

Yours sincerely,

Roberto Frontini
President
European Association of Hospital Pharmacists

John Chave
Secretary General
Pharmaceutical Group of the European Union

Jane Nicholson
Executive Director
European Industrial Pharmacists Group