

**MR MADELIN- INFORMED PATIENT**  
**PHARMACEUTICALS – INFORMATION TO PATIENTS**

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Responsible official: M. Takki/C5. (SANCO) tel: 53453

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**MESSAGES TO PASS**

**1. Introduction**

- This event focuses on looking at the legal framework on information to patients on pharmaceuticals. However, before we start discussing that, we should reflect the wider challenges in the area of health today and in particular, the information challenges.
- Europe has changed dramatically over the last 50 years – and faces many new challenges.
- For example:
  - The population is ageing.
  - Citizens demand more information and better care, while healthcare budgets are already stretched.
  - The new and innovative health technologies are changing the way we diagnose and treat patients.
  - And there are wide disparities in the health status of citizens and quality of healthcare between different Member States, regions and social groups.

**2. Two major health policy areas aim to address these public health and societal challenges: health services and EU health strategy**

**Health services**

- In the area of health services, a proposal for a directive on health services and cross-border care is expected to be adopted by the end of the year.
- This proposal will provide clarity to patients about possibilities to choose healthcare providers abroad. The proposal will also make clear who is responsible for quality and safety of care in cross-border settings. And it will improve information provision to patients on possibilities of cross-border care.

## Health strategy

- Another important framework is the new EU Health strategy. The White Paper – “Together for Health” – (adopted 23 October) sets out a number of areas which can be used to support the empowerment of citizens in health.
  - For example, e-Health applications can increase opportunities to gain access to information
  - In this context, the Commission is developing a comparable European Health Information and Knowledge System to support policy making to reduce inequities in health.
- Against this background, it is clear that instead of narrowing our sights to information on just one special area of health technologies – pharmaceuticals – we should consider how health related information can be provided in such a way that citizens and authorities can trust it.

### **3. Pharmaceutical Forum has been a useful platform for stakeholder collaboration to build trust**

- Building trust is a key element of the Pharmaceutical Forum. The Forum is just one of the collaborative platforms in which we are involved. The others – the nutrition and alcohol platforms which I chair – also bring together Member States and key stakeholders with the aim of finding new ways to tackle common challenges.
- The two platforms I just mentioned were set up because there were no collaborative partnerships or platforms to discuss concerns and ways forward in the area of nutrition or alcohol policies.
- The Pharmaceutical Forum, however, was built on the earlier G10 process and a wide range of existing activities linked to the issues of the Forum. It did not start from scratch but aimed to take a fresh look at the outstanding G10 recommendations on information to patients, relative effectiveness assessments and pricing and reimbursement policies.

### **4. Information to patients under the Pharmaceutical Forum**

- On information to patients the Forum has so far achieved two main objectives;
  1. First, the Forum members have developed concrete work, namely on access to information on health care settings; a set of core principles of good quality information; and tools for patients to distinguish good information from bad. The Forum working group (and Austria in particular) is now developing a methodology to implement the quality principles.

2. The second objective has been to contribute to the legislative process on information to patients on pharmaceutical products, led by my colleague Heinz Zourek.

- We are all familiar with the call that patients need more and better information. But how can we know what they want?
- The Pharmaceutical Forum is a unique platform precisely because it seeks to answer questions like that. How? Because patients are members of the Forum, and so have a direct route to put their views across. So do the other members, such as the Member States and the pharmaceutical industry.
- Last spring a public consultation was held to disseminate information on the ongoing activities of the working group under the Pharmaceutical Forum, and to provide an opportunity for all stakeholders to give their views and comments on the a way forward for future work within the framework of existing EU legislation.
- The responses are summarised in a report available on the Forum website. In a nutshell, there was general support for the quality principles developed by the information to patients working group. Plus, there were a number of suggestions in relation to strengthening or developing further the principles with a view to ensuring a high level of quality of information.
- What is also very clear is that the ending of prohibition on advertising on prescription only medicines is not wanted. This is a clear message from the patient groups, consumers as well as the industry.
- Following several years of discussion, we now know very clearly what everyone wants – improved information and better access to information. But what remains open, is the issue of how this can best be achieved.

## **5. The legislative review on information to patients is a separate process**

- The separate process on revising the legal framework is the focus of the today's discussion. A colleague from Enterprise will no doubt make remarks on the state of play of that process.
- In my view, the Forum has developed some useful elements to be considered when discussing the legal framework.
- For example, the quality principles which were agreed by the high level Pharmaceutical Forum are a good example of trust in the area of pharmaceutical information and therefore could be used when possible validation mechanisms or systems to govern information are considered.
- Furthermore, the Forum working group is now focusing on looking at good practices at national level regarding partnerships. Sweden, with a specific example of a partnership called FASS, and a number of other Member States, have developed or are in the process of developing partnerships which bring

together information on pharmaceutical products. The Forum has provided a mechanism to share those experiences.

- In addition, the Forum has provided a platform at expert and political levels to discuss what today's Europe needs and how far all players are committed towards achieving an improved information framework for European citizens. The Forum has demonstrated that it all comes down in the end to one central issue – trust.
- The key question seems to be whether we can distinguish advertising from information in a way that meets the apparent desire of EU society not to see advertising of medicines to the general public.
- This is not a new issue – there are many other areas where the distinction between information and advertising has been discussed.
- Take one example – the updated TV without Frontiers Directive – lays down some basic principles governing advertising, and at the same time simplifies and liberalises rules on inserting advertising in TV programmes and on new advertising techniques.
- Although some issues are remote from each other – such as information on medicines and advertising of toys for St Nicolas on TV – there are some common elements such as setting up principles. We should also look at other areas and learn from those as well.
- The Forum process has provided a useful platform to discuss a wide range of issues related to information on treatments and pharmaceuticals. However, the Forum process is too rigid and the structure is too heavy. As an approach, it is a good way of building trust but it cannot alone establish a new way ahead on information to patients.
- To conclude, trust and confidence have to be ensured in any system which provides information to European citizens. I think today's meeting is useful to discuss the principles, and how these can be applied in today's Europe. Once the principles have been established, we can move on to discuss the details.

**End**

**1305 words**