Nicolas Rossignol
European Commission
Directorate-General Enterprise and Industry
Unit F2 'Pharmaceuticals'

THE FUTURE OF PHARMACEUTICALS FOR HUMAN USE IN EUROPE

First of all it is great that there is this kind of public consultation on this important issue. And this kind of consultation is especially good in the spirit of Transparency Initiative.

Just to remind about Transparency Initiative [1] it should be noted that there has been a public consultation based on COM(2007)185 [2]. The answers of COM(2007)185 consultation [3] are publicly seen and I propose to follow actively the Transparency Initiative.

This consultation was very interesting and it lead me to spend some time to increase understanding of the pharmaceutical field in Europe.

Since this is an opinion of a citizen without vast knowledge of pharmaceutical field it should be handled mercifully.

According to instructions opinion part of this opinion paper is less than six pages.

Annex 1 holds information of copyright, licence and disclaimer.

Best Regards,

Jukka Rannila
citizen of Finland

signed electronically

1 Transparency Initiative: http://ec.europa.eu/transparency/index_en.htm
2 The COM(2007)185 consultation: http://ec.europa.eu/transparency/revision/index_en.htm
3 Answers to the COM(2007)185 consultation: http://ec.europa.eu/transparency/revision/contributions_en.htm.

THE FUTURE OF PHARMACEUTICALS FOR HUMAN USE IN EUROPE

OPINIONS

Question 1: Do you agree with the analysis of the main challenges outlined above? Do you see other challenges?

Answer 1:

There was many kind of challenges mentioned in the introduction to the question. Here is a collection of challenges [4] I noticed:

- preparation for pandemic situations
- globalisation of the pharmaceutical sector
- problems in the internal markets of European Union
- the threat of European Union not being in forefront of pharmaceutical development in the near or distant future
- the threat of some link failing in medicine development, tests, approval or post-approval follow-up
- the increasing pressure to publish more information about medicines, e.g. patients demanding information.

Since this is contribution of an individual citizen this opinion does not cover all commercial aspects in the pharmaceutical industry.

But in case of preparation for pandemic situations there should of course be legal and practical measures to produce, stock and distribute medicines in the case of pandemic situation also in countries like Finland. As a concerned citizen I hope that early warning systems are in place and functioning.

In the the case of internal market it is quite disturbing that there are inefficiencies between member states. And from the point of an average citizen it is little bit disturbing to think that approval and other processes in home country might not be as efficient as they should be. The quality of approval and other processes should be good [5] in every member state – no doubt of that.

The pressure to release more information about certain medicine is totally understandable. Since the level of education is higher than before and that combined with amount of information in the electronic networks there are situations when an average doctor might know less of a certain medicine than a patient who has spent hours or even days (may be weeks?) reading information of that specific medicine depending on what kind of user rights she/he has to different electronic databases. There has been a consultation [6] of information given to patients and this is nothing new to people in this area. The problem is like said the quality of information.

4 There might be also problems if a challenge is understood to be a problem.
5 Good is a point of view and probably there are many views.
6 http://ec.europa.eu/enterprise/phabiocom/comp_pf_consult_2007.htm

European Public Assessment Reports [7] (EPAR) for authorised medicinal products for human use is quite good collection of information. My main concern that is that kind of information readable for all medicines sold in Europe. Since EPARs are maintained by the European Medicines Agency [8] (EMEA) it seems that kind of information is not distributed from all medicines. Browsing the directives and web pages it seems that EMEA is not all-powerful centralised agency since it has certain functions and probably many want keep it that way.

But EPARs are well done and there should be that kind of centralised database of all other medicines sold in European Union area. One interesting feature there is in EPARs. I browsed some of them and did not find mentioning about scientific literature done before. I might be wrong but is it responsibility of manufacturers to give all scientific references of certain medicine before approval. If that is already done there is no problem. On the other hand they are products not yet in the market and there might be no or very limited amount of references. This is just a small detail and possibly misunderstanding.

Anyway. Centralised database like EPARs, with same quality or even extending the current quality, of all medicines sold in European Union would alleviate the problem of distributing information. In practical terms this might not done easily since the approvals are different around the Europe like said in the introduction and collecting that kind information afterwards is rather unrewarding task noting the large amount of medicines sold.

Then competitiveness of European pharmaceutical industry? Well. In the case of USA it can be said that is really an industry when looking the clinical trial databases [9] since there is lot of activity all the time. It seems that their processes to find persons to clinical trials are quite streamlined at least according to web pages. Just came to my mind that is it easier to conduct clinical trials and recruit people to them in USA than in Europe? I don´t know the situation but it is not restricted to make stupid questions. But the service level of those USA databases and possibilities to take part in those clinical trials of specific disease you might be suffering is just overwhelming. Is service level that good in Europe?

Question 2: Do you see other areas than those already targeted by the Commission where regulatory action should be taken?

Answer 2:

The pharmaceutical web page [10] of the Commission is just huge collection of everything possible.

Just thinking the information processing capability of an average medical field professional... Presuming that most of them are quite normal people there is a lot of to learn and that takes time. The EudraLex [11] web page created for collections of the current pharmaceutical legislation is a

7 http://www.emea.europa.eu/htms/human/epar/eparintro.htm
8 http://www.emea.europa.eu/
9 http://www.clinicaltrials.gov/, http://www.centerwatch.com/ and http://www.fda.gov/oashi/clinicaltrials/default.htm
10 http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm
11 http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm

masterpiece of good administration. EudraLex probably makes life easier in many cases.

However. May be there could be some sort of readability research done about that rather large community legislation concerning pharmaceutical field. I don´t mean necessarily creating new legislation or altering legislation. But just thinking those barriers to efficiency all information should be presented as readable as possible. May be just giving legislation is not the only way. And on the citizen point of view it would be nice to read clearer more human-readable text first before digging into legal details. Digging into legal details is inevitable but it can be helped with good introduction.

Question 3: What would you suggest as concrete measures to ensure the safety of medicines supplied in the EU, addressing in particular counterfeit medicines, and provision of high quality and affordable medicines also to third countries?

Answer 3:

Now I have admit that I can not provide an opinion of this issue. I have never encountered counterfeit medicines and this issue totally unknown to me.

Question 4: What can be done to improve Europe's international competitiveness?

Answer 4:

Probably this is about competitiveness of pharmaceutical industry in Europe.

There have been established a small but hopefully efficient research centre in the health care district where I come from and that centre is conducting those clinical trials with patients. Like I indicated before I wondered if the clinical trials with humans are organised as efficiently as the international best example found. Is work of these kind research or testing units somehow coordinated? I don´t mean creating some central agency with all administration. How they distribute their work loads of these tests? Is it pure competition or is it voluntary cooperation? Is it organised in the best way? Just pure wondering from an average citizen.

I case of Finland there are new laws [12] about creating a system in following years where – at last from the point of citizen – patient information should move smoothly over different organisation boundaries and there should not be constant gaps of information and that unbelievable great fuzz with unclear records from the view of patient. It will be seen how this system will work in the near future and probably there will be some problems to get system work in practise. But in principle it could be possible to have statistics of different diseases.

I don´t mean selling customer information to pharmaceutical companies and guarding denial of that is a constant task. But may be they could buy a postal service when information about those clinical

12 Laki sosiaali- ja terveydenhuollon asiakastietojen sähköisestä käsittelystä 9.2.2007/159, http://www.finlex.fi/fi/laki/ajantasa/2007/20070159, and Laki sähköisestä lääkemääräyksestä 2.2.2007/61, http://www.finlex.fi/fi/laki/ajantasa/2007/20070061

trials is posted. That postal service should be conducted be public sector but buying a postal service delivery could be private initiative. When there is some sort of approval for test then it should be matter of independent citizen to approve or not to approve to take part in some test.

But the idea presented above would mean that patient information record systems should be in good order around the Europe. It might be that situation in as bad as current situation in Finland. And thinking of pharmaceutical companies they can not affect to that. If patient information record systems are not in order it is impossible to use them for that postal service idea mentioned.

There is of course personal data protection issues and some legal points to be checked. And of course there is the hard reality and this idea might be just a theoretical exercise.

Question 5: What can be done to foster convergence and transparency as regards pricing and reimbursement in the EU?

Answer 5:

I was wondering before is there any centralised database of all medicines sold in the Europe. It might be too huge administrative exercise to create that and combine all monetary information to it but just came to my mind.

Question 6: Do you think the current EU regulatory framework can accommodate emerging technologies like regenerative and personalised medicine, as well as nanobiotechnology?

Answer 6:

Probably those new technologies are creating challenges to all stakeholders.

In the spirit of Better Regulation initiative changes to legislation should be efficient and simple. All I can say that following the field and law preparation should be quite efficient.

Commission is at least trying like the SINAPSE® system is indicating. May be that kind of system could be used more efficiently in the law preparation concerning pharmaceutical field and its advancement. Of course avoiding a mess with thousands of documents means creating structured processes.

Jukka Rannila
citizen of Finland

signed electronically

ANNEX 1

DISCLAIMER

Legal disclaimer:

All opinions in this opinion paper are personal opinions and they do not represent opinions of any legal entity I am member either by law or voluntarily. This opinion paper is only intended to trigger thinking and it is not legal advice. This opinion paper does not apply to any past, current or future legal entity. This opinion paper will not cover any of the future changes in this fast-developing area. Any actions made based on this opinion is solely responsibility of respective actor making those actions.

Political disclaimer:

These opinions do not represent opinions of any political party. These opinions are not advices to certain policy and they are only intended to trigger thinking. Any law proposal based on these opinions are sole responsibility of that legal entity making law proposals.

These opinions are not meant to be extreme-right, moderate-right, extreme-centre [13], moderate-centre, extreme-left or moderate-left. They are only opinions of an individual whose overall thinking might or might not contain elements of different sources. These opinions do not reflect past, current or future political situation in the Finnish, European or worldwide politics.

These opinions are not meant to rally for a candidacy in any public election in any level.

Content of web pages:

This text may or may not refer to web pages. The content of those web pages is not responsibility of author of this document. They are referenced on the date of this document. If referenced web pages are not found after the date when this document is dated that situation is not responsibility of the author. All changes done in the web pages this document refers are sole responsibility of those organisations and individuals maintaining those web pages. All illegal content found on the web pages referenced is not on the responsibility of the author of this document and producing that kind content is not endorsed by the author of this document.

13 Based on the Finnish three-party system there is phenomenon called extreme-centre in Finland.