LAUSUNTO

Lausuja: Kymenlaakson sairaanhoitopiiri / Eettinen toimikunta / 14.12.2009
Aihe: European Commission/Assessment of the functioning of the ”Clinical Trials Directive” 2001/20/EC

Euroopan komission arviossa ”European Commission/Assessment of the functioning of the ”Clinical Trials Directive” 2001/20/EC” tarkastellaan EU-direktiivin 2001/20/EC aiheuttamaa käytäntöä ja sen seurauksia. Tärkeimmät havainnot ovat seuraavat:

1. Arviossa todetaan direktiivin parantaneen huomattavasti potilasturvallisuutta EU:n alueella tehtävissä ihmiseen kajoavissa tutkimuksissa.

2. Arviossa todetaan direktiivin lisänneen huomattavasti hallinnollista työtä tutkimusprojekteissa.

3. Arviossa käsitellään syntynyttä tilannetta, jonka mukaan lisääntynyt ihmiseen kohdistuvan tutkimuksen hallinnollinen työ olisi edistänyt tutkimuksen teettämistä kolmansissa maissa.

4. Arviossa todetaan se tosiseikka, että ihmiseen kajoavien tutkimusten eettiset periaatteet kirjanneista dokumenteista ja säädöksistä ei ole pulaa ja se, että ongelmat ovat valvonnassa ja eettiset periaatteet ja käytännöt kirjanneiden säädösten ja sopimusten noudattamiseen pakottamisessa.

5. Arviossa pohditaan ratkaisumalleja syntyneisiin kysymyksiin.

Pyynnöstä lausun otsikossa mainitusta arviosta seuraavaa:

Consultation item nr. 1: Can you give examples for an improved protection? Are you aware of studies/data showing the benefits of Clinical Trial Directive?

It is of course not possible to prove the effects, because before the directive different studies were under work than after the directive’s acceptance, but it is clear that the principles of the Clinical Trial Directive have improved the safety of the subjects.

Consultation item nr. 2: Is this an accurate description of the situation? What is your appraisal of the situation? (This refers to the problem of multiple and divergent assessments of clinical trials in multi-centre studies performed in several EU countries)

As it is stated, it is an exception that a clinical trial gets divergent decisions in different Member States. The description is quite correct.

Consultation item nr. 3: Is this an accurate description? Can you quantify the impacts? Are there other examples for consequences? (This refers to the problem of increased administrative costs and to the longer delays in starting the clinical trials, when the sponsor has to wait for the authorisation of the study in each Member State)

The sponsors’ administrative costs certainly increase when there are more requirements for the administration. In that sense, the description is accurate. In what comes to the centralised authorisation vs. authorisation in the member states, it is not necessarily only positive to centralize

assessments. There are examples of centralised assessments and authorisations in the world history. It should be remembered that the purpose of the Clinical Trial Directive is not to ensure smooth data collection and easy administration, but to protect the citizens. Although authorisation of the study itself is certainly possible by one body and this practice certainly would make the process fluent, there may be regional differences in the views in such a wide area as the EU is.

Consultation item nr. 4: Can you give indications/quantifications/examples for the impact of each option? Which option is preferable? What practical/legal aspects would need to be considered in further detail?

Option 1: Reliance on voluntary cooperation of NCAs
Option 2: Community-wide streamlining of NCA-authorisation process for clinical trials

The option 2 is preferable, because it is better controllable, and a certain level of control is necessary to avoid problems. The procedure in case of disagreement of one Member State should be determined clearly in a Directive.

Consultation item nr. 5: Can you give indications/quantifications/examples of for the impact of each option? Which option is preferable? What practical/&legal aspects would need to be considered in further detail?

Option 1: One-stop shop for submission of assessment dossier
Option 2: Strengthening networks of national Ethics Committees involved in multinational clinical trials
Option 3: Clarifying the respective scope of assessment of NCA and Ethics Committees

The power of the EU is in that it is “a union of states”, not a federation. This makes is a strong enough entity in many areas, but does not abolish variation. From this point of view option 2 would be preferable. However, of course the most efficient alternative would the option 1.

Consultation item nr. 6: Is this an accurate description of the situation? Can you give other examples? (This refers to the inconsistent implementation of the Clinical Trials Directive)

The description is accurate enough.

Consultation item nr. 7: Is this an accurate description of the situation? Can you quantify the impacts?

The description is accurate.

Consultation item nr. 8: Can you give indications/quantifications/examples for the impact of each option? Which option is preferable? What practical/legal aspects would nbeed to be considered in further detail? In particular, are the divergent applications really a consequence of transposing national laws, or rather their concrete application on a case-by-case basis?

Option 1: Reviewing the Clinical Trials Directive with a view to clarifying provisions, where necessary
Option 2: Adopting the text of the Clinical Trials Directive in the form of a Regulation

When giving a regulation, it should be kept in mind that there should be resources to control the execution of the regulation. As it is stated even in this Public Consultation Paper that there are difficulties in controlling and enforcing the Clinical Trial Directive, these resources should be strengthened first before increasing the

power of the centralized legislation in this area of ethical issues. How could the controlling and enforcing resources be strengthened by increased centralization? To increase controlling and enforcing of the Clinical Trial Directive, competent ethical committees are needed in large numbers in each area of the Community.

Consultation item nr. 9: Can you give examples for an insufficient risk-differentiation? How should this be addressed?

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Consultation item nr. 10: Do you agree with this description? Can you give other examples? (Requirements not always adapted to the practical circumstances, e.g. the requirement of the Directive for a single sponsor)

This is true in one sense, but it should be remembered that the sponsor has also responsibilities, which are detailed in the Directives. If there are several sponsors, it may be difficult to determine, who of them is responsible for what and in what degree. The present state is satisfactory in that if there de facto are several sponsors, e.g. a group of researchers, they may form a legal body together to form the single sponsoring agent.

Consultation item nr. 11: Can a revision of (implementing) guidelines address this problem in a satisfactory way? Which guidelines would need revision, and in what sense, in order to address this problem?

A revision of the implementing guidelines would be sufficient. In what comes to the requirement for insurances, there is no need to change this requirement, if the citizens are to be protected from harms.

Consultation item nr. 12: In what areas would an amendment of the Clinical Trials Directive be required in order to address this issue? If this was addressed, can the impacts be described and quantified?

An amendment to a Directive could be useful to adjust it to the experiences obtained, if its purpose is to protect the citizen.

Consultation item nr. 13: Would you agree to this option and if so what would be the impact? (Refers to a review of the existing Directive and excluding clinical trials of "academic" sponsor from the scope of the Directive)

This is not preferable.

Consultation item nr. 14: In terms of clinical trials regulation, what options could be considered in order to promote clinical research for paediatric medicines, while safeguarding the safety of the clinical trial participants?

It is important to keep the parents involved, because they are the best safeguards of their children. The benefit of the children is here much more important than a fluent data collection.

Consultation item nr. 15: Should this issue be addressed? What ways have been found in order to reconcile patient's rights and the peculiarities of emergency clinical trials? Which approach is favourable in view of past experiences?

This is a difficult issue, because when a person is at the edge of life and death, it is only natural to allow only a necessary touch. Secondly, if one is possibly about to die, she or he should allowed to be in peace, if possible. Only in cases, where it is probable that the new treatment modality would be of more benefit to the subject than the old ones, it is acceptable to use it, but if it is known for sure beforehand, no trials are needed. One possible solution would be that those who are willing to take part to any trial in the moment of emergency, would keep a card informing about this in their wallet, like the permissions to organ donations in case of death.

Consultation item nr. 16: Please comment? Do you have additioin information, including quantitative information and data? (Refers to ensuring compliance with Good Clinical Practices [GCP] in clinical trials performed in third countries)

Correct. Nothing to add.

Consultation item nr. 17: What other options could be considered, taking into account the legal and practical limitations? (Refers to options for address the issue of research in third countries)

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Consultation item nr. 18: What other aspect would you like to highlight in view of ensuring the better regulation principles? Do you have additional comments? Are SME aspects already fully taken into acoount?

It is necessary to keep the local ethical committees fully functional to ensure the control and enforcing of the Clinical Trial Directive.