

INTERIM REPORT

DR VESNA KOBLAR, THE CONSULTANT

PROJECT:

TECHNICAL ASSISTANCE IN DEVELOPING A NEW LAW ON
PHARMACEUTICALS IN R.MACEDONIA, HARMONIZED WITH EU
LEGISLATION

Draft "0" of the Law on Medicinal Products and medical Devices was drafted after the first in-country visit, taking into consideration all already agreed items presented in the Inception Report.

After 15 of very intensive working days the Draft "0" of the Law on Medicinal Products and medical Devices was drafted and sent to the Working Group established in MoH for collaboration in developing the new Law (hereinafter: WG) on January 21:

Draft "0" - See ANNEX I of the Report

The proposed Draft "0" is harmonized with basic provisions of the EU acquis on medicinal products and medical devices e.g. Dir.2001/83/EC; CR 726/04/EC; Dir.2001/20/EC;Dir. 93/42/EEC; Dir.385/90/EEC; Dir 98/79/EC; Dir 89/105/EEC; and some ECJ cases. Other provisions of the abovementioned pieces of legislation and some provisions of the comitology directives will be transposed by by-laws of the Law on Medicinal Products and Medical Devices.

The Law was drafted with aim to follow EU criteria, only some provisions that could have a negative impact on functioning health system or impact on economic operators if introduced overnight, are planned either to be implemented later by transitional provisions or to be slightly modified in order to fit the system and to protect public health.

So, several provisions were just partially harmonized with the EU acquis on medicinal products and medical devices because of special needs arising from the existing situation on the area of pharmaceuticals that were presented during the first in-country visit. Those provisions are justified in line with detailed discussion with the WG.

Second in-country visit was organized from January 28-February 1.

The visit was aimed to present the Draft "0" of the Law on Medicinal Products and Medical Devices to the WG together with the introductory Seminar on basic principles of the EU pharmaceutical and medical devices acquis that has been presented on the Day 1 of the visit and seminar on EU regulatory approach that was given together with relevant chapters of the Law.

Justifications of all provisions were provided chapter by chapter and article by article.

The WG was again extremely motivated and helpful in providing necessary comments and data that were either taken into consideration or if not, the extensive justification and explanation was provided.

The Law covers medicinal products and medical devices and also establishes the Agency for Medicinal Products and Medical Devices.

Provisions on establishing the Agency for Medicinal Products and Medical Devices are pure national provisions and are given as a recommendation only.

There were some concerns expressed by the WG about the translation of the Draft (0) Law from English to Macedonian language because specific regulatory terms were not translated properly. The WG will give the input in order to improve the translation by using specific terms used in the regulatory area.

Detailed description of the work, the outline and content of the Proposal are presented below in the form of the Draft 1.

The WG will prepare the improved translation of the Law in Macedonian language and add some national provisions to the section on inspection as soon as possible. Dr Koblar will be review the English translation of changes made by the WG and prepare the final input to the new Law as well as the List of necessary By-laws with their draft outline content as requested for the Progress Report.

Dr Koblar will also be in contact with the WG during further procedure of the adoption of the Law.

The next in-country visit is planned for the second half of April 2007. The aim of the visit will be to present draft outlines of the necessary by-laws as agreed during the 2nd visit.

Detailed description of the work on the Law - Draft "1"

Comments and modifications made during the second in-country visit are presented in the form of Draft "1" with track changes and comments, see: ANNEX II OF THE REPORT

Short description of the main items:

I General Provisions

Slight modifications of several definitions were made and three definitions were added: see comments introduced in the text of the Draft 1

II Agency for Medicinal Products and medical Devices

It was explained that the Chapter is to be regulated according to national preferences only. The proposal is just the basic idea on how to create provisions on the Competent Authority for Medicinal Products and Medical Devices. There's no EU model for Competent Authority for medicinal products and devices, but the nature of its work according to the mission statement, the required level of flexibility and professional independence influenced establishing of Competent authorities in EU Member States as professionally independent and financially either independent or partially financed from budget.

Provisions on pharmacies were added as activities of the Agency because of basic provisions on pharmacies were added in Chapter III by the WG. Dr Koblar was of the opinion that pharmacies should be regulated separately, but it was explained that the existing situation requested some basic provisions on pharmacies to be added in this Law.

Slight modifications of wording of some articles were introduced: see comments introduced in the text of the Draft 1

III Medicinal Products

Some modifications of wording were introduced following very useful comments and proposals from the WG: See comments introduced in the text of the Draft 1

Compassionate use provision was added by dr Koblar

It was agreed that standing and ad hoc Committees of the Agency should have advisory role.

It was stressed that transitional periods should be introduced, particularly for data exclusivity period, for upgrading of dossiers ect

The WG preferred widening of the scope of generic substitution in pharmacies and introduction of generic prescription: see comments introduced in the text of the Draft 1 and modifications of relevant wording.

It was decided that authorization of clinical trials of investigational medicinal products that have not been authorized in Macedonia is requested. Notification procedure is left for all other investigational medicinal products. This approach slightly differs from dir 2001/20/EC that requires authorization procedure only for medicinal products listed in the annex of CR 726/04/EC. The reason for this small modification results from the existing situation that requires more strong approach in this field e.g. authorization procedure for a wider range of medicinal products.

It was agreed that provisions on parallel import will be introduced after 5y transitional period has elapsed.

It was suggested by the group that even authorized medicinal products should have an import authorization. Dr Koblar did not agree on making obstacles for authorized products because the marketing authorizations should have also a role of import licence. It was explained that it would not be enough for custom officers and that the existing situation requires this double checking. The provision has not been modified (yet) and the modification is going to be introduced by the WG if necessary.

Provision on retail sale in pharmacies was added by the WG as explained before.

Provision on procedure in the case of quality defect was added by dr Koblar.

The chapter on MP Waste was deleted because it has already been regulated by another law

IV MEDICAL DEVICES

Some modifications of wording were introduced following very useful comments and proposals from the WG: See comments introduced in the text of the Draft 1

Conformity assessment procedure and CE certificated issued by EU Notified Bodies are recognized in Macedonia

Conformity assessment procedure for medical devices not certified by EU Notified Bodies was adjusted to national needs and possibility for national Conformity assessment bodies was introduced as well as possibility for Medical Devices Committee to assess medical devices not certified in the EU or by national assessment bodies. Insisting on marketing of medical devices assessed in the EU or CE marked only, would have a negative impact on the market, so the possibility to keep many commonly used devices of a good quality but not assessed in the EU but in Macedonia following the same criteria, was introduced.

Possibility for retail sale of medical devices in specialized stores was confirmed.

CE mark is to be recognized in Macedonia.

The conformity mark used in the R of Macedonia is introduced for products that are not CE marked, based on the conformity certificate issued in the R of Macedonia following the EU criteria

V INSPECTION

Provisions for pharmaceutical inspection and inspection for medical devices were put together in the same chapter because of their similarity

Some provisions concerning rights and obligations of inspection were modified according to comments given by the WG. WG will introduce further changes after consultation, if necessary.

Provisions on inspection are mainly national provisions that shall be in accordance with provisions of the Law in other Chapter. Only basic provisions are mentioned in EU directives

VI PENAL/OFFENCE PROVISIONS

Chapter is to be completed by the WG, mainly by lawyers

VII TRANSITIONAL AND FINAL PROVISIONS

Chapter is to be completed by the WG, mainly by lawyers

All other detailed comments are presented in the text of the Draft 1, all modifications of the text of the Draft 1 as track changes in the ANNEX II of the Report

The Draft "1" outline and content of new Law is presented for the Interim Report without track changes in the ANNEX III of the Report

Concordance of provisions with existing basic EU legislation is presented in the ANNEX IV of the Report

Prepared by

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