



4th Annual Pharmaceutical and Health Conference for SEE, 10 November 2010 Belgrade, Serbia

LATEST DEVELOPMENT IN THE REGULATORY ENVIRONMENT FOR GENERICS IN THE REPUBLIC OF MACEDONIA

MINISTRY OF HEALTH
BUREAU FOR MEDICINAL PRODUCTS
Head of MP Department
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COMPETENT AUTHORITY & MP LEGISLATION

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- BUREAU FOR MEDICINAL PRODUCTS

web: www.reglek.com.mk

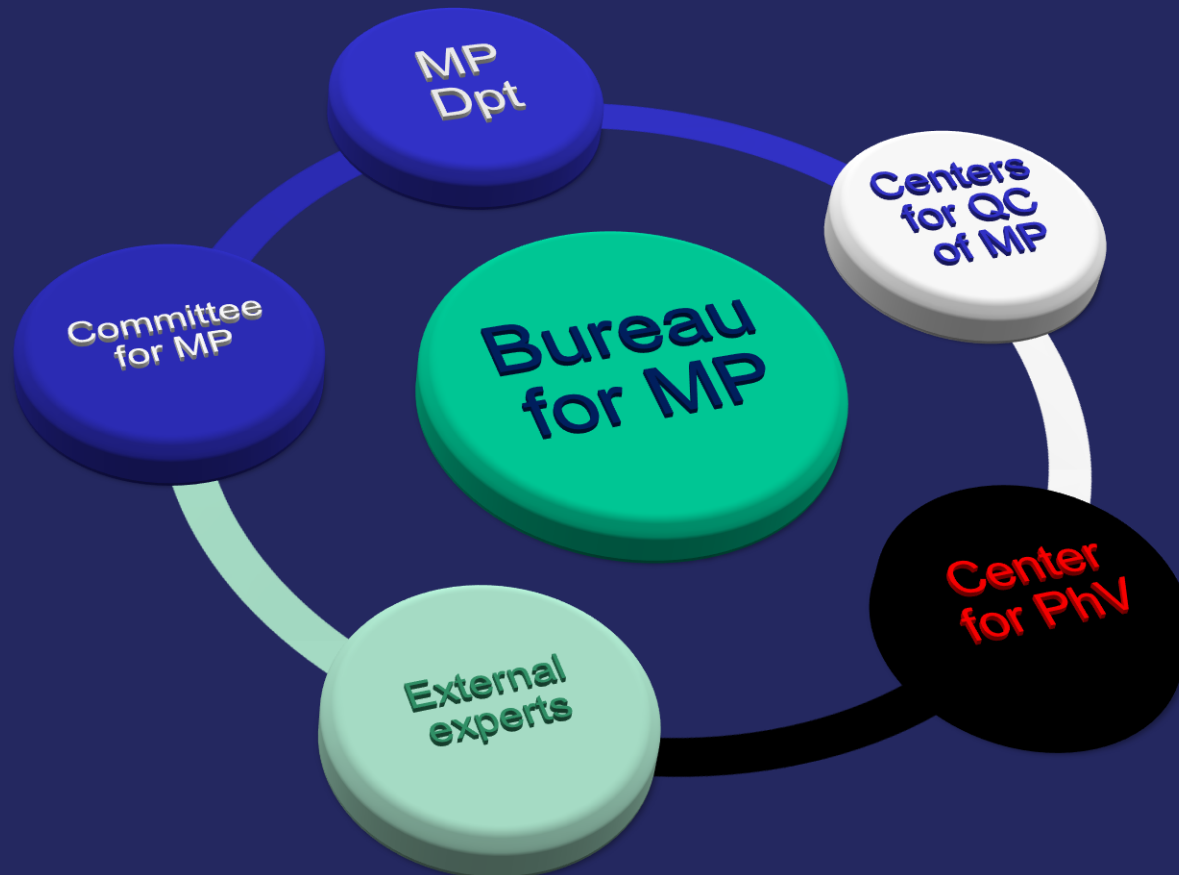
- Current Law on MP&MD (in force since 13.09.2007)
- Amendments of Law on MP&MP (adopted in July 2010)
- Full system of bylaws (applied 26 in the field of MP)

- Implementation phase



DRA RESPONSIBILITIES

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MARKETING AUTHORISATION

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TOTAL NUMBER OF MP AUTHORIZED
IN THE REPUBLIC OF MACEDONIA = **3150**

Past 1 year period:

- >280 applications for MA
- >490 applications for renewal
- >3250 applications for variations
- >57 applications for transfer of MA



LEGAL PROCEDURES TIME DURATIONS

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- **GRANTING of MA :**
 - >max. 210 days, for national procedure,
 - >90 days, for MP that already have got a MA in EU country with DCP or MRP,
 - >15 days, for MP approved in Central procedure through EMA)
- **RENEWAL of MA : max. 90 days**
- **VARIATIONS : (Type I, notifications – 30 days, Type II, approvals – 60 days)**
- **VALIDITY of MA : 5 YEARS**

TIMING OF SUBMISSION AN APPLICATION:

- Length of Data exclusivity: 8 years
- Length of Market exclusivity: 2 years
- Full Implementation of formula 8+2+1
(no transitional provisions for DE & ME)



BOLAR PROVISION

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- Bolar Provision part of Pharmaceutical Law
- The activities covered by Bolar Provision
- Supplementary Protection Certificate (SPC) part of Patent Law



CHOICE OF REFERENCE PRODUCT

- Bureau for MP accepts the bioequivalence studies from the other countries
vs RMP
if design of statistical data

- The samples are tested during the MA procedure
- Testing is not necessary for all MP
- Simplification if
 - >Product has got MA in the EU with centralized procedure
 - >Product has got MA in the EU with MR procedure
 - >Product has got MA in the EU with DC procedure

- CTD format is compulsory
- Dossier can be in English
- SmPC (Summary of the Product Characteristics) of generic medicine must be identical to the SmPC of the originator



POST AUTHORISATION 1/2

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- VALIDITY PERIOD of MA = 5 years
- Once renewed, the MA shall be valid for an unlimited period of time
(apply after 5 years of the date 13.09.2007)



POST AUTHORISATION 2/2

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- **UPGRADING** the documentation for the old products
(obligatory after date 01.01.2010)
- When to submit an application for upgrading



PHARMACOVIGILANCE 1/2

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- Periodic Safety Update Report (PSUR)
obligatory
- PSUR submission cycle

-Organization of the PhV system:

- >National Center for PhV

- >Division for PhV in Bureau for MP

- I-VI month 2010:

- >53 notifications on local level (9 from the local market and 44 from the Clinical Trials)

- >1250 notifications from the market in other countries



QC INCLUDE:

- Regular QC
- QC of the first batch
- Extraordinary QC
- Specific QC

Simplification



QUALITY CONTROL 2/2

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2 AUTHORIZED LABORATORIES for QC

LAST YEAR:

- >Regular QC–348 analysis
- >Extraordinary QC –16 analysis
- >Control of the first batches after getting MA –268 analysis

Prices of MP (National decision)

- >uniform system of prices for the medicinal products on prescription (Rp)
- >Free prices—for the nonprescription MP (BRp)

MANNER OF PRESCRIPTION & DISPENSING

- GENERIC SUBSTITUTION is allowed
- List of essential medicines (277 INN)
- Reimbursement list (948 items)



REGULATORY SKILLS

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TRAININGS

>IPA Project with **EMA**

>**WHO** training activities

>Program with **Uppsala Monitoring Centre**