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

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BUREAU FOR MEDICINAL PRODUCTS
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# COMPETENT AUTHORITY & MP LEGISLATION



- BUREAU FOR MEDICINAL PRODUCTS

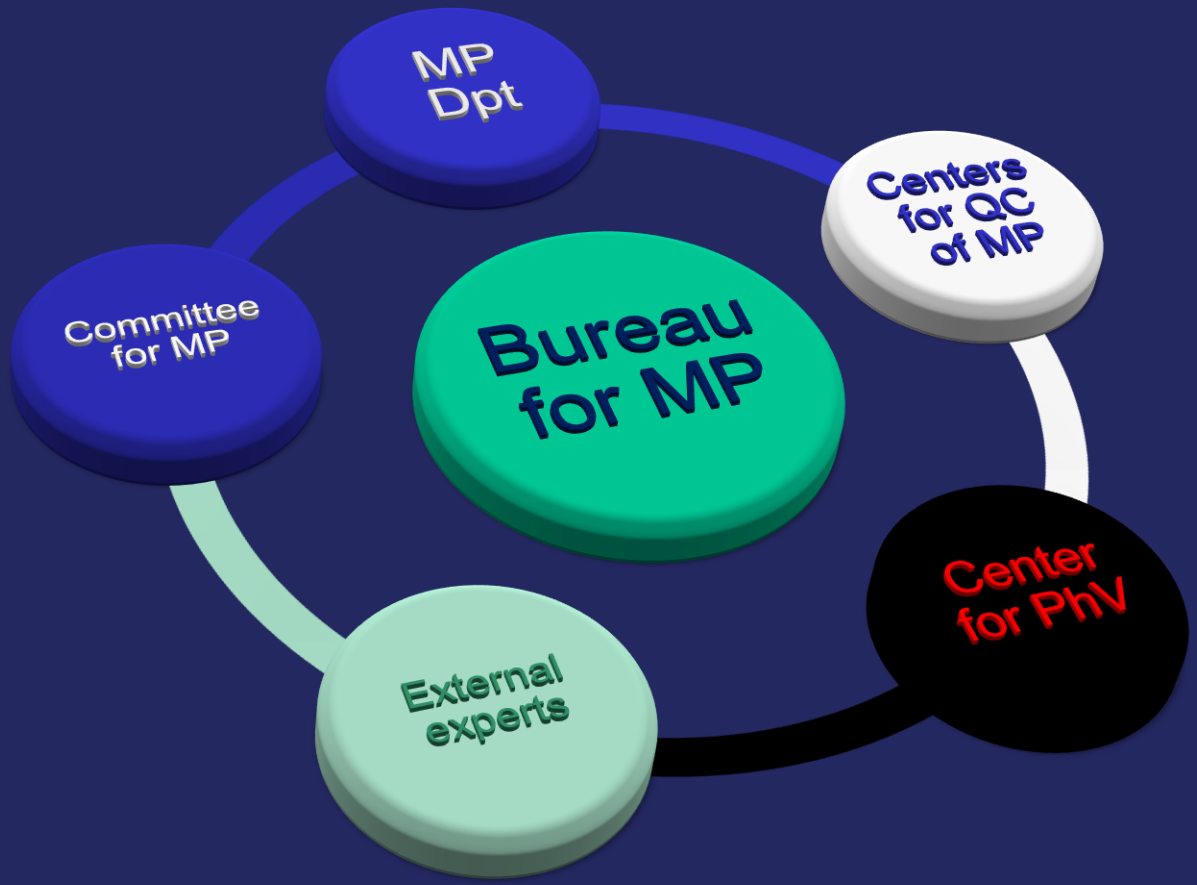
web: www.reglek.com.mk

- 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





# MARKETING AUTHORISATION



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



- 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 SUBMISION 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 PROVİSİON



- 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

# SAMPLES OF THE MP



- 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

# FORMAT OF THE DOSSIER



- 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



- 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



- UPGRADING the documentation for the old products

  (obligatory after date 01.01.2010)

- When to submit an application for upgrading

# PHARMACOVIGILANCE 1/2



- Periodic Safety Update Report (PSUR) obligatory

- PSUR submission cycle

# PHARMACOVIGILANCE 2/2



-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

# QUALITY CONTROL 1/2



## QC INCLUDE:

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

Simplification

# QUALITY CONTROL 2/2



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)

# TRAININGS

>IPA Project with **EMA**

**>WHO** training activities

>Program with **Uppsala Monitoring Centre**