Réunion d'information
Informatievergadering

19/05/2009

Programme

- **Introduction (Annemie Decostere, pharma.be)**
- **Présentation de la nouvelle structure de l'AFMPS (Greet Musch & Wim Penninckx, AFMPS)**
- **Plan d'action pour le traitement accéléré des dossiers d'enregistrement et pour remédier au Backlog (AFMPS) : 1ère partie**
  - ✓ **Indicateurs et points d'action (Vanessa Binamé)**
  - ✓ **Variations sans impact sur l'AMM light (Ann Verhoye)**
  - ✓ **Implémentation des décisions de la CE, des recommendations européennes (Sophie Colyn)**
  - ✓ **Evaluation SPC, PIL et labelling en cours de procédure (Christelle Beeckmans)**
  - ✓ **Test de lisibilité, Changement de Titulaire, Inactivation – base légale, Lettre de retrait (Vanessa Binamé)**

Inleiding

Annemie Decostere

Adviseur Volksgezondheid pharma.be

Présentation de la nouvelle structure de l'AFMPS

Greet Musch
Directeur général DG PRE AFMPS
&
Wim Penninckx
Directeur général a.i. DG POST AFMPS

Federal Agency for Medicines and Health Products (FAMHP)

The New Structure of the FAMHP

Pharma.be – Febelgen

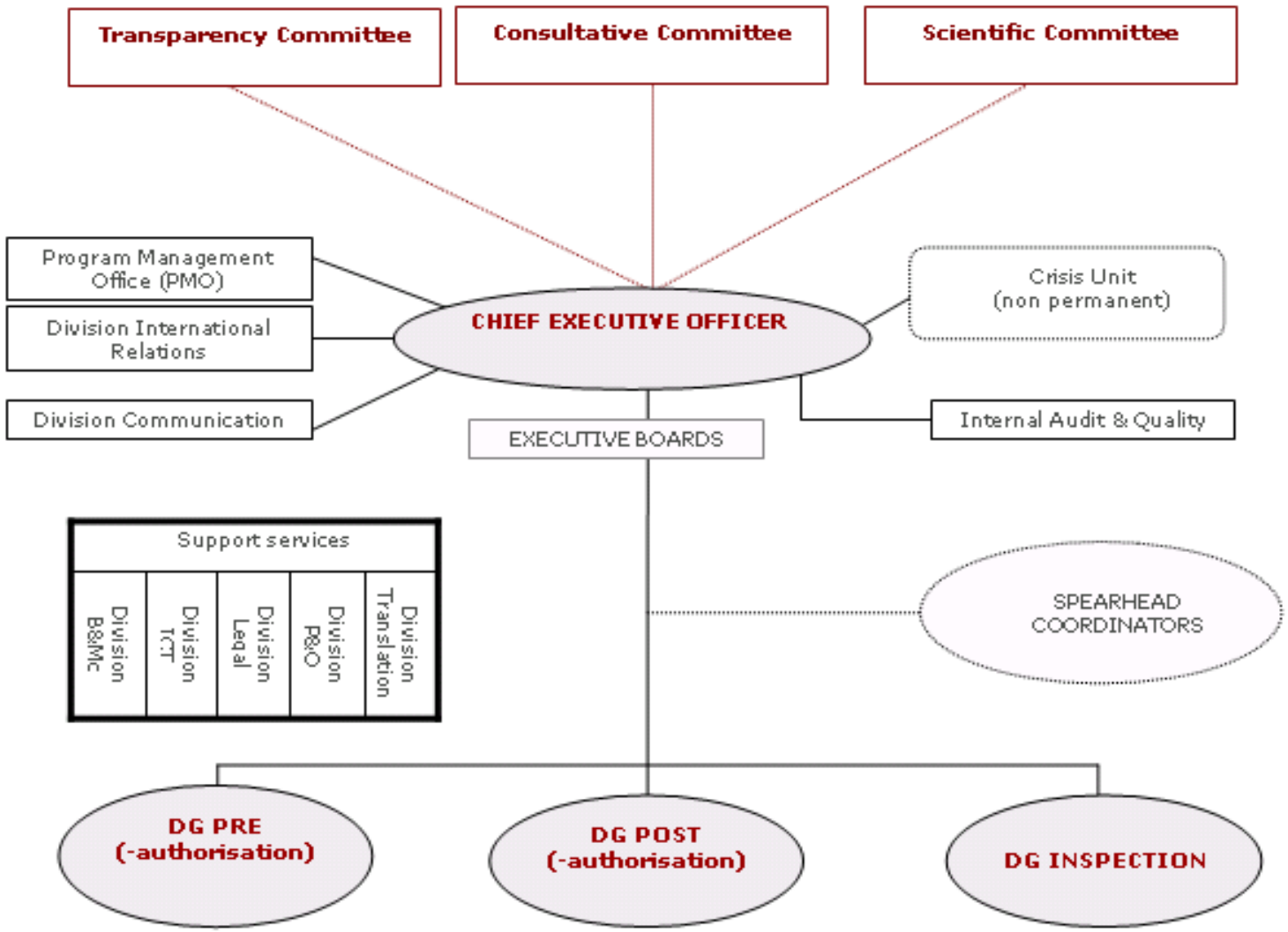
Infosession

19/05/2009

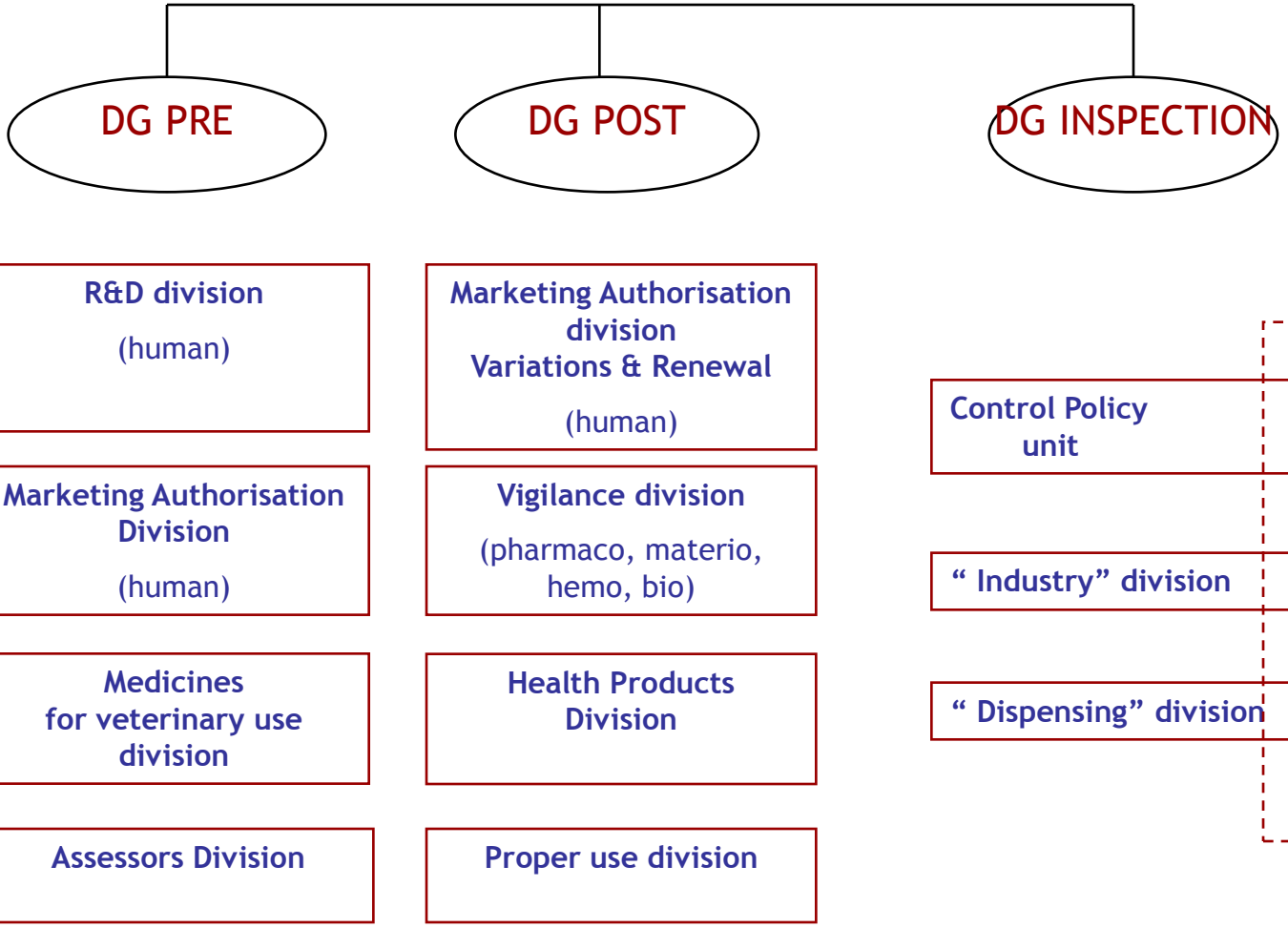
Greet Musch, PhD
Director- General Pre-authorisation

Wim Penninckx, PhD
Director-General, a.i. Post-authorisation

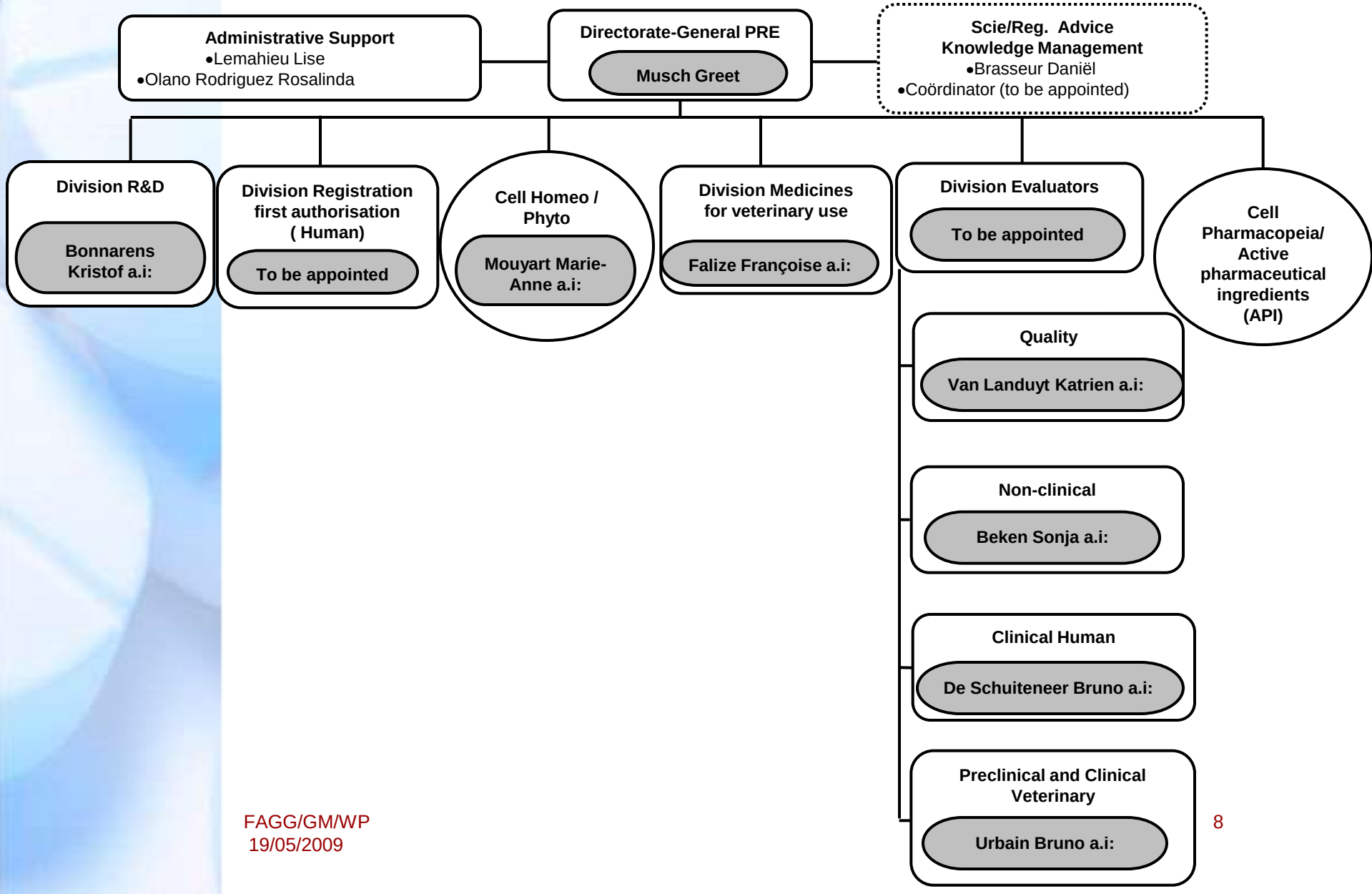
1.1. The new structure



1.2. Divisions of the FAMHP



2. Current Organogram DG PRE



3. DG PRE : Core activities

3.1. Focus on division Registration first authorisation (Human)

First request for a marketing authorisation

- -National procedure
- -Mutual Recognition and Decentralized procedure **(MRP/DCP)**

The complete handling of Centralised procedures
(PSUR's excepted)

3. DG PRE : Core activities

3.2. Focus on division Evaluators

The evaluators perform evaluation tasks in function of the procedures managed by all the different departments of the three DGs, with the exception of assessment related to PSUR's and "risk management plan".

4. DG PRE: Objectives

4.1 Focus on Division Registration first autorisation (Human):

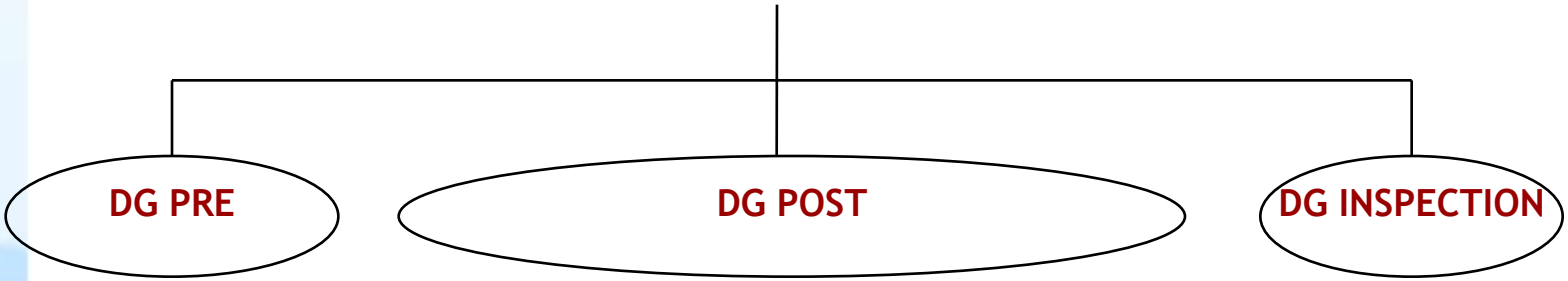
- Extraction from ex departement Registration (« as is «)
- Backlog of remaining files : action plan
- New structure (« to be «)
- Focus on development of support for Centralised Procedures (CoExc)

4. DG PRE : Objectives

4.2 Focus on Division Evaluators

- Review and validation of acceptance criteria for all the different assessment tasks
- Implementation of a time monitoring system
- Inventory and optimisation of participation in key (Inter)national platforms (eg EMEA)
- Inventory and optimisation of training
-Concept of pro-active capacity planning
-QA of assessment work

5. DG POST : Structure



- Marketing Authorisation Division
  Variations & renewals
- Vigilance Division
- Health Products Division
- Proper Use Division

6. DG POST : Core activities

6.1. Focus on division MA – Variations and renewals

- Maintenance of the Marketing Authorisation
  - ✓ *Variations to MA (National and Mutual Recognition)*
  - ✓ *Renewals of MA*
  - ✓ *Revision validation*
  - ✓ *Withdrawal of MA*
- Parallel import
- Call centre

6. DG POST : Core activities

6.1. Focus on division Vigilance

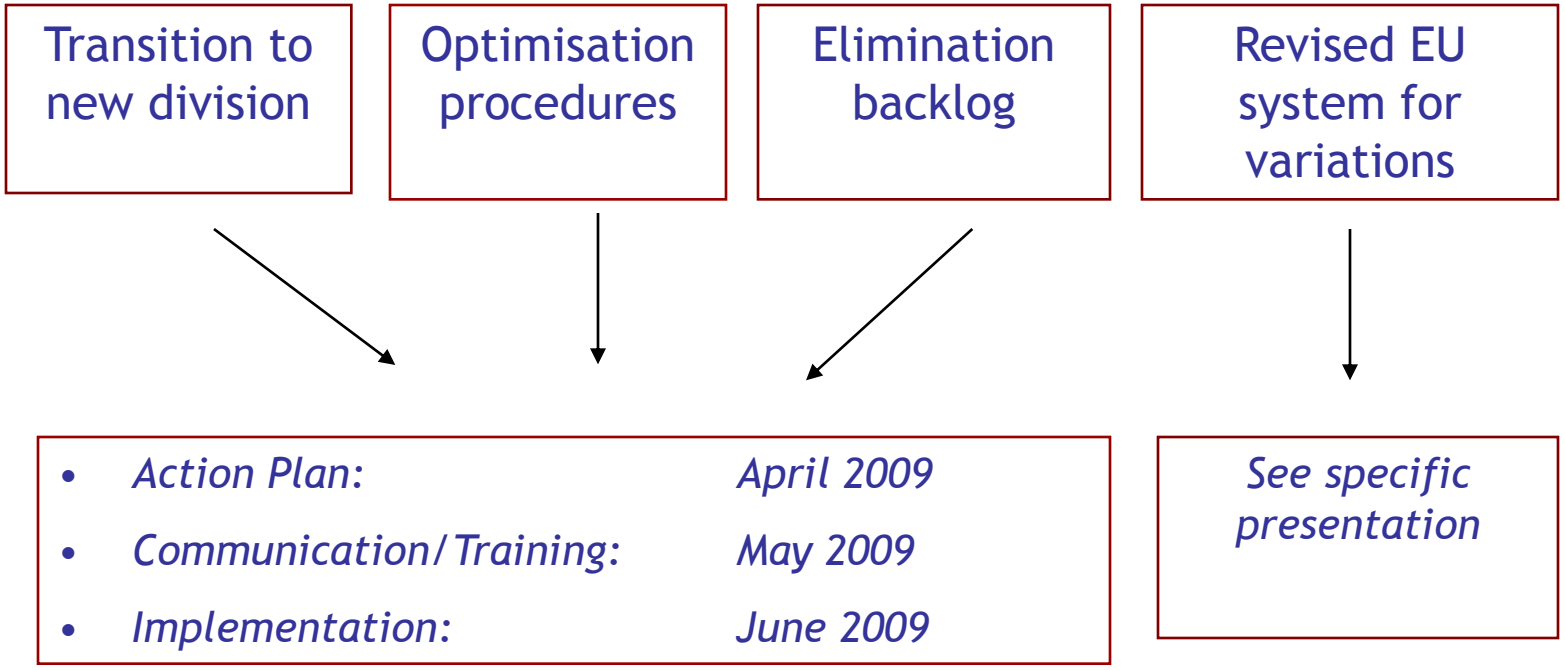
Collection and assessment of data regarding adverse effects /incidents, and implementation of measures to prevent those.

- *Medicinal products for human and veterinary use*
  (Pharmacovigilance)
- *Medical devices*
  (Materiovigilance)
- *Blood products*
  (Hemovigilance)
- *Cells & tissues*
  (Biovigilance)

In scope of action plan

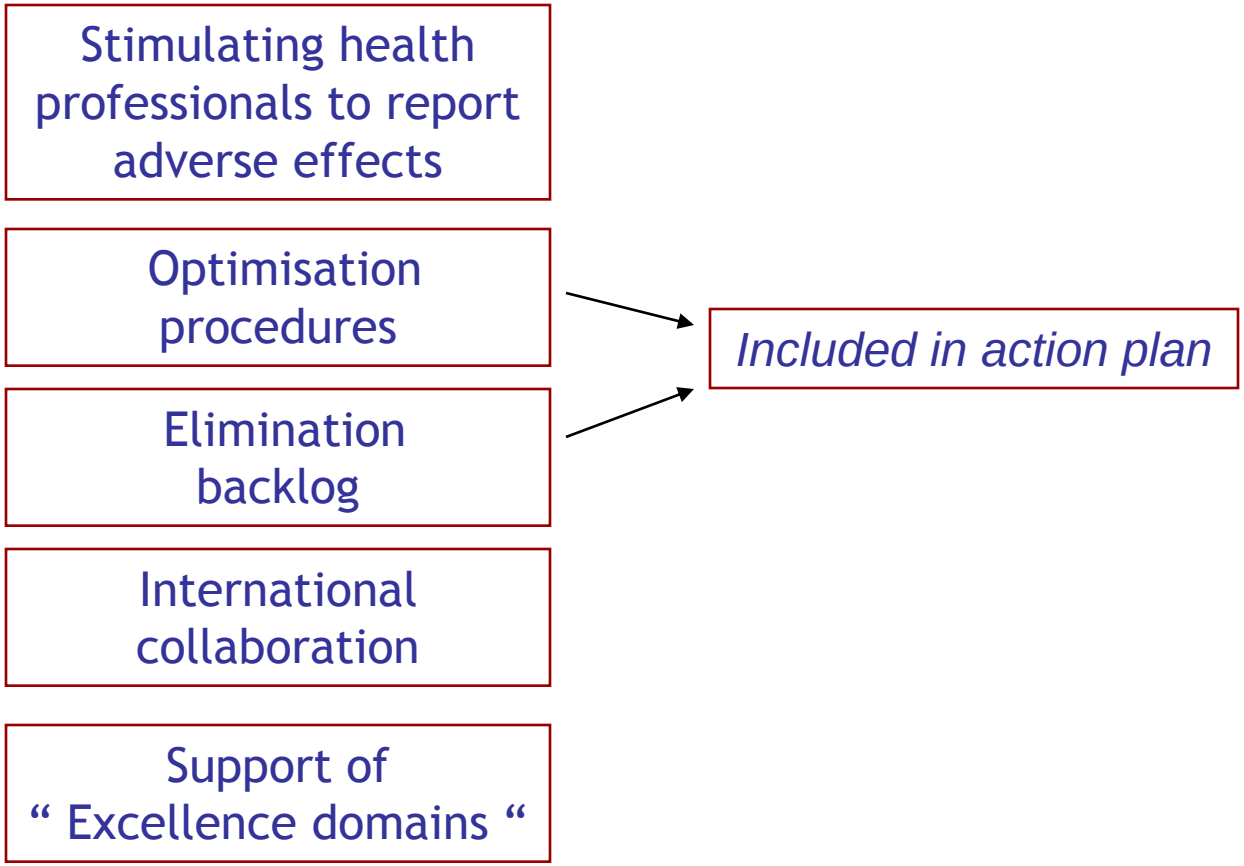
7. DG POST : Objectives

7.1. Focus on division MA – Variations and renewals



7. DG POST : Objectives

7.2. Focus on Pharmacovigilance



Thank you for your attention
Suggestions?

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Actieplan voor het versneld behandelen van registratiedossiers en ter remediëring van de Backlog - 1ste deel

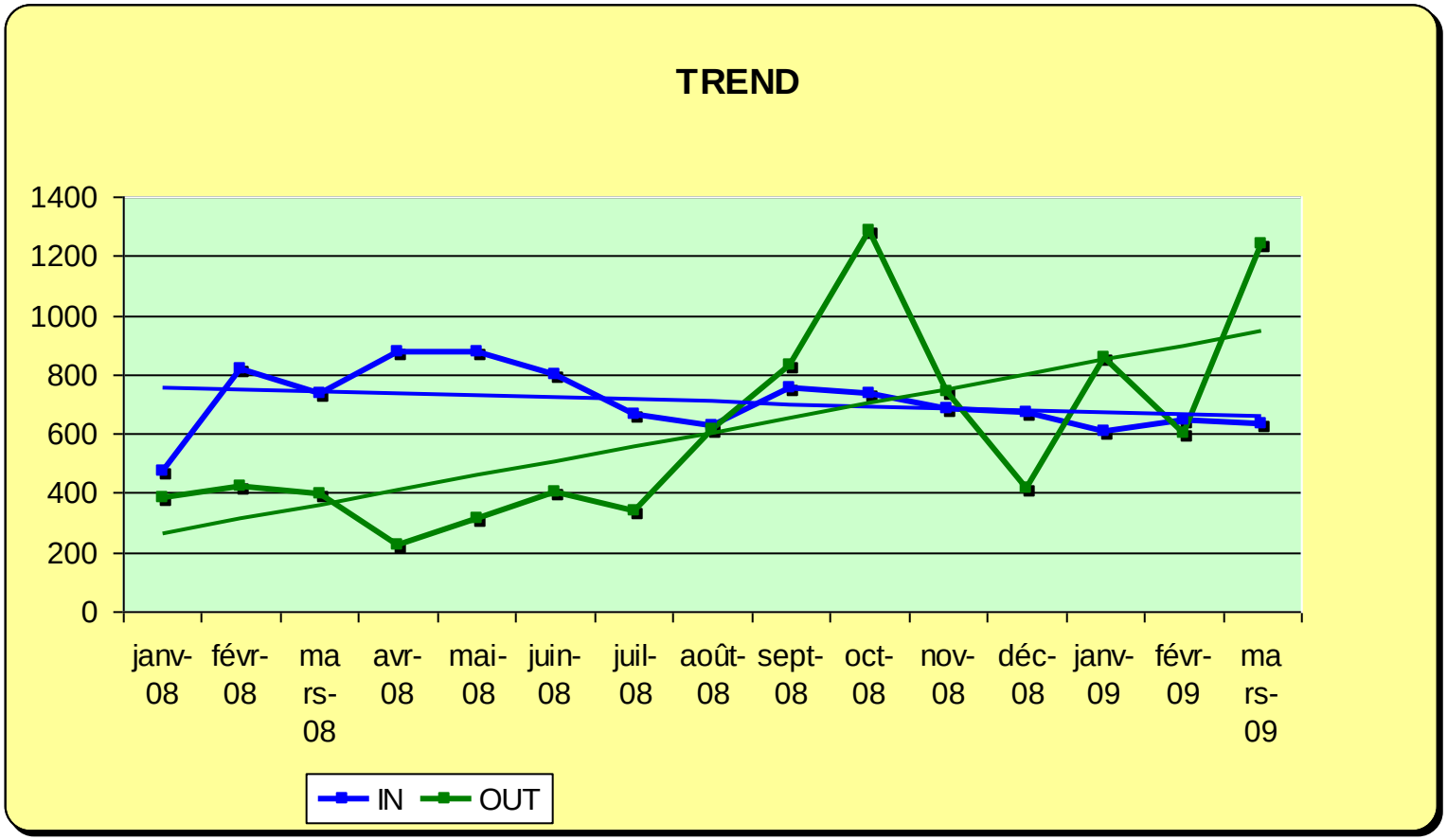
Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Indicators

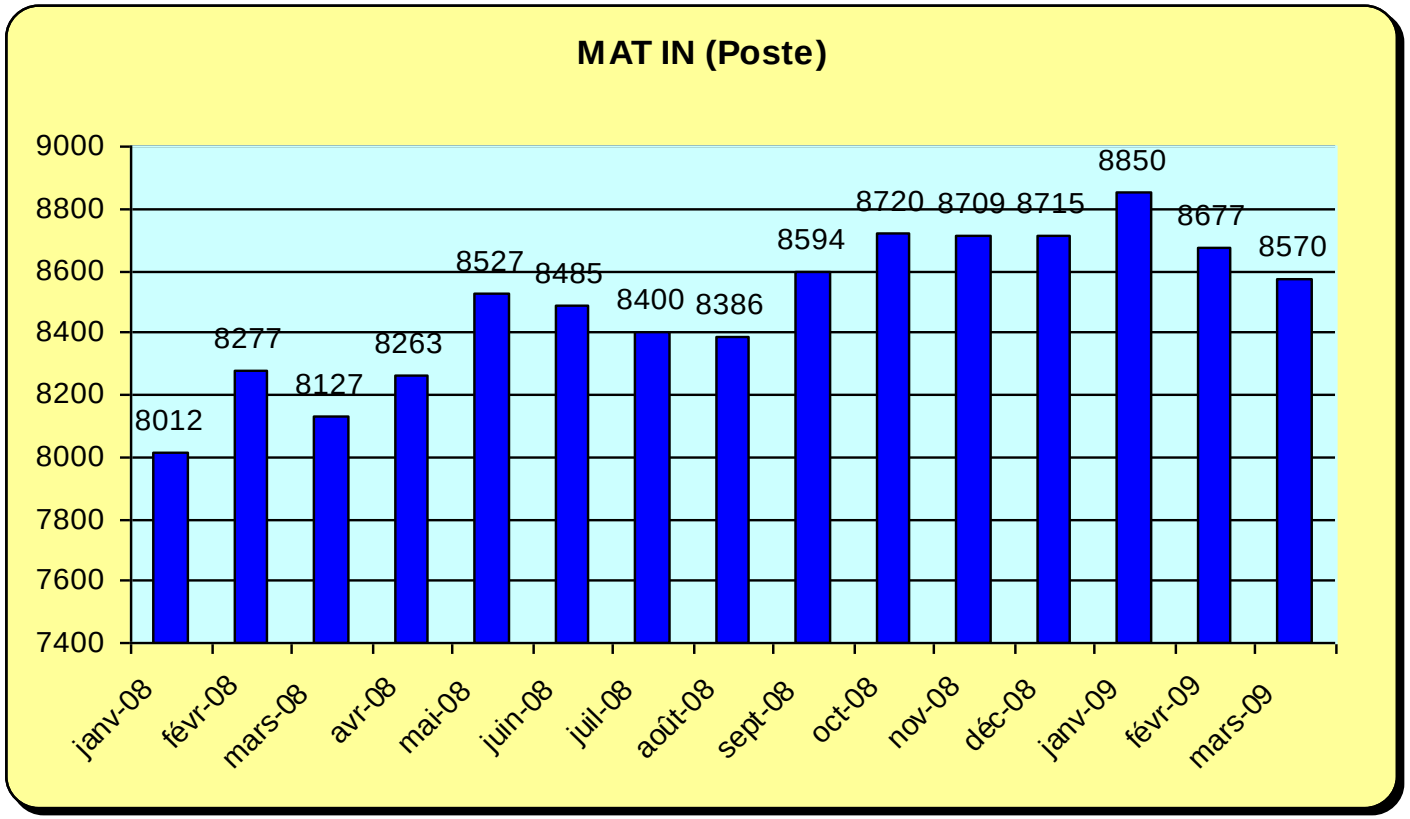
Vanessa Binamé

19/05/2009

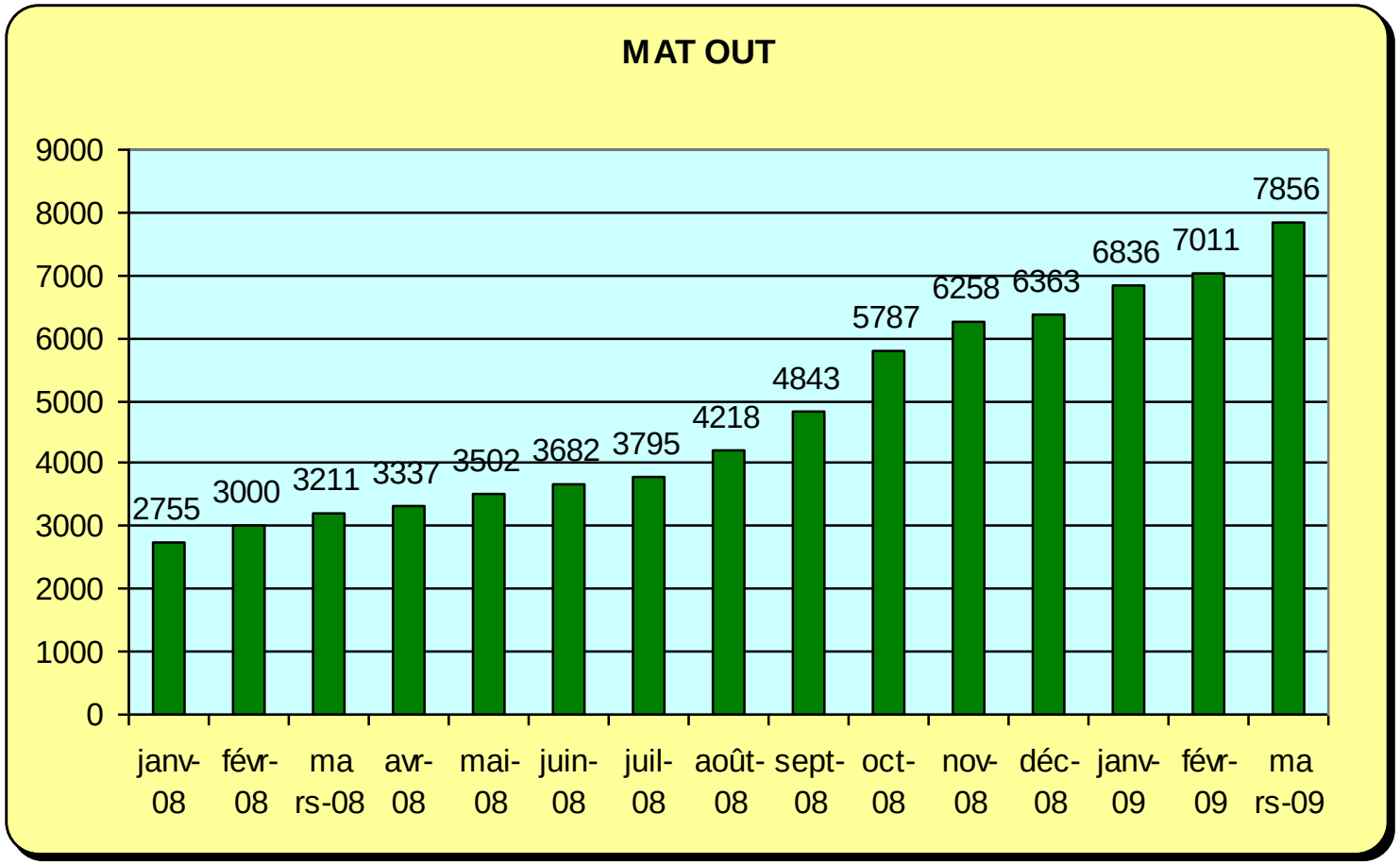
IN / OUT - Trend from 01/01/08



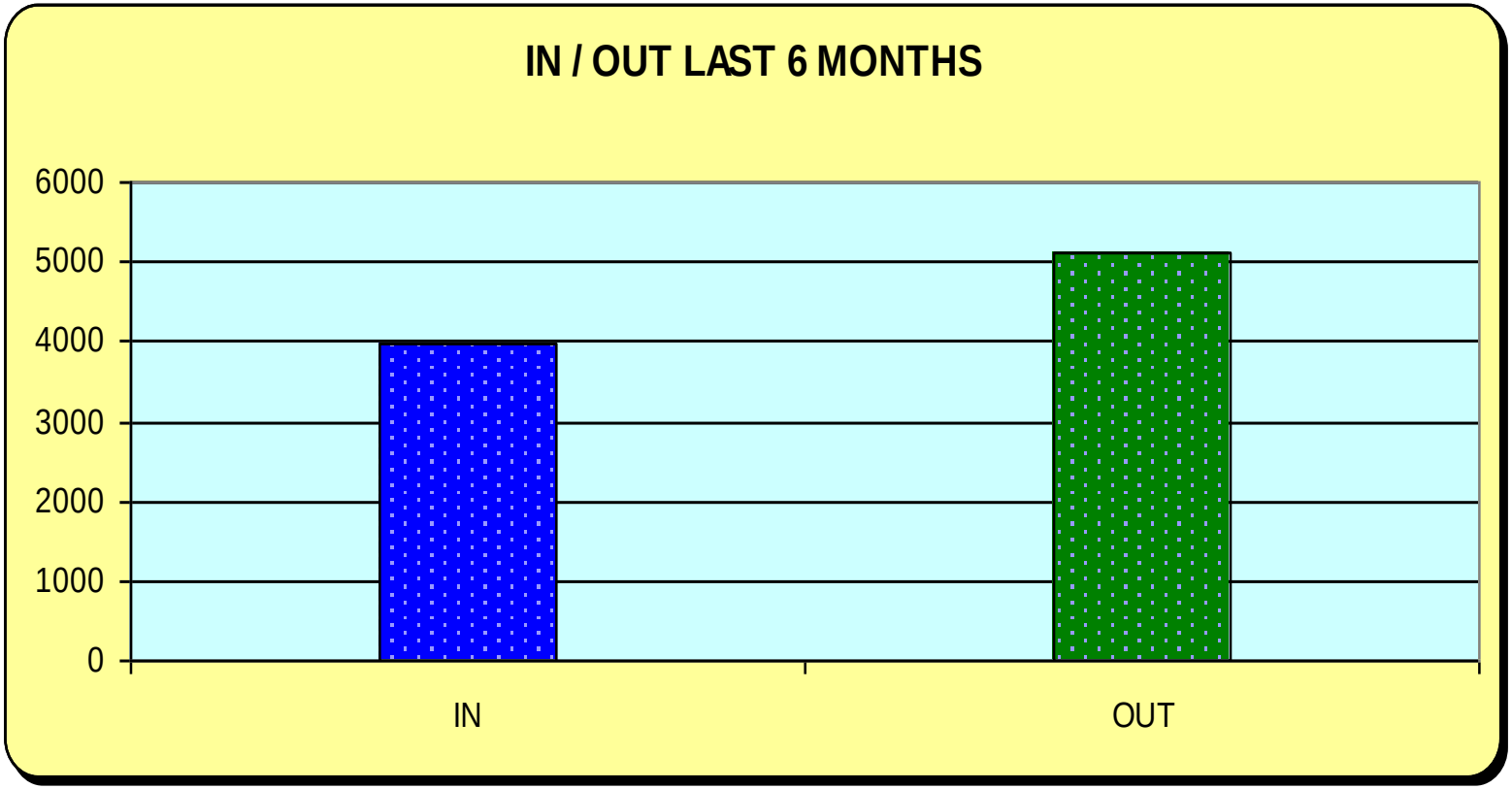
MAT IN FROM 01/01/08



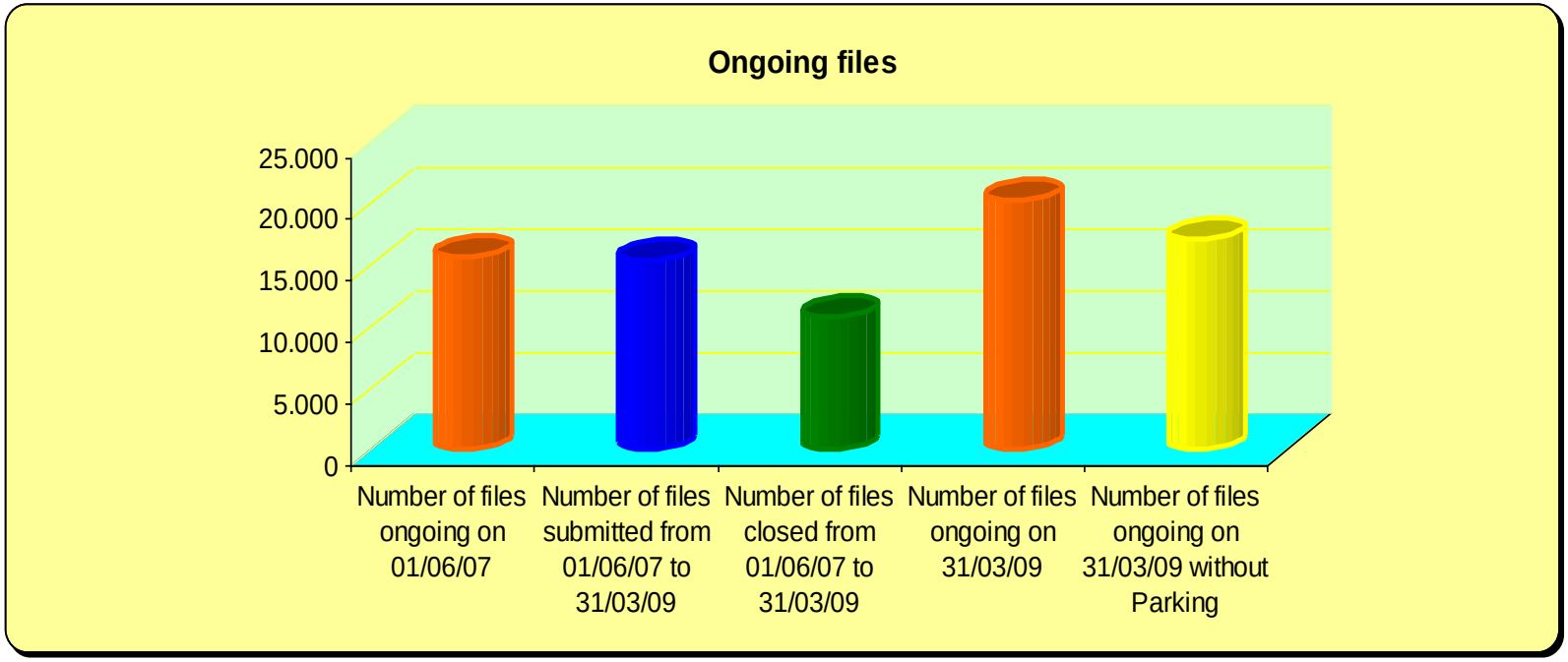
MAT OUT FROM 01/01/08



IN / OUT from October 2008



Ongoing Files on 31/03/09



Amongst the ongoing files: 3129 are in the parking
⇒ implemented by the MAH without waiting the administrative closing

Federal **A**gency for **M**edicines and **H**ealth **P**roducts (FAMHP)

Action Plan

Vanessa Binamé

19/05/2009

ACTION PLAN – Decision making process

Adopted during the Steering Committee “Backlog” in February 2009

Composition of the Steering Committee “Backlog”

- Representative of the Minister of Health
- FAMHP
- Pharma.be
- FeBelGen

ACTION PLAN - Presentation

1. **Letter of withdrawal**

Impact for the industry: all the applications regarded as needless will be withdrawn by the applicant

Implementation date: 30/06/09

Indicators: number of dossiers withdrawn

ACTION PLAN - Presentation

2. **Implementation of Referral, Class Labelling and European recommendations**

Impact for the industry: faster national implementation of specific clinical variations: articles 30 and 31 referral, class labelling, European recommendations, articles 29 of Paediatric regulation. The dossier submitted has to be in accordance with the wording adopted at European level. If not, the dossier will be refused by FAMHP

Implementation date: 30/06/09

ACTION PLAN - Presentation

Indicators:

- Number of dossiers submitted according to an European Commission Decision, European recommendation
- Number of dossiers refused since they are not compliant with the European Commission Decision, European recommendation.
- Number of dossiers closed within 30 days

ACTION PLAN - Presentation

3. Readability Test

Impact for the industry: all authorised package leaflets should be subject to a readability test before 2012. The submitted reports will be assessed by the FAMHP based on a risk analysis approach.

Implementation date: the criteria for the risk analysis approach should be adopted by 30/06/09

Indicators: number of dossiers assessed, number of dossier which are not compliant with the legal requirements

ACTION PLAN - Presentation

4. Variations without impact on light AMM

Impact for the industry: all variations without impact on the light AMM will be closed without sending the documents to the MAH since there is no amendment to the decision of granting the marketing authorisation resulting from these procedures.

Implementation date: 30/06/09

Indicators: number of dossiers without impact on light AMM submitted and closed on a monthly basis

ACTION PLAN - Presentation

5. **Assessment of SPC, PL and labelling during the procedure**

Impact for the industry: no more questions on the SPC, PL and labelling during the closing phase. All questions should be addressed and correctly answered during the evaluation phase of the NP, MRP or DCP.

Implementation date: 30/06/09

ACTION PLAN - Presentation

Indicators:

- Number of procedures for which the SPC, PL and labelling are assessed on a monthly basis
- Quality of the documents submitted:

  number of questions sent during the procedure and related to the SPC, PL and labelling or concerning standard terms, QRD template, etc.…
- If still applicable: number of comments sent during the closing phase

ACTION PLAN - Presentation

6. Inactivation of files

Impact for the industry: legal basis for the automatic withdrawal of inactivated dossiers

Implementation date: November / December 2009

Indicators: number of dossiers withdrawn

ACTION PLAN - Presentation

7. Risk analysis of the Marketing Authorisation process

Impact for the industry: risk analysis for the backlog dossiers in assessment phase and proposals to reduce this backlog

Worksharing: Implementation of decisions adopted in other MS for the same medicinal product

Implementation date: Analysis foreseen for 30/06/09

Indicators: reduction of the backlog “assessment”, number of dossiers closed thanks to worksharing

ACTION PLAN - Presentation

8. Autocontrole

Impact for the industry: the MAH will be responsible to check the conformity of its file to the FAMHP requirements.

Implementation date: Brainstorming foreseen during the 2nd semester of 2009

Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Backlog actionplan
Variations without impact on light AMM

Ann Verhoye

19/05/2009

Variations without impact on light AMM

- Background
- Scope
- Way of proceeding
- Communication to the applicant on dossier output
- Timeline
- Project within DG POST

Variations without impact on light AMM

- **Background:**
  - Actual project '**update variatietabel**' (MRP IA-IB and NP IA without impact on datamodel):

Start:	1/07/2008 with 1 FTE
Today:	14% of closed dossiers result from this project
Conclusion:	this kind of project is performant
Goal:	Enlarge scope of the actual project

Variations without impact on light AMM

- **Scope:**
  - Variations concerning changes which do not affect the light AMM, the PIL, the SPC and labelling.
  - Backlog dossiers of type NP IA-IB, MRP CMS IA-IB, MRP CMS II analytical.
  - New dossiers uploaded starting from 1/6/9 of type NP IA-IB, MRP CMS IA-IB, NP II analytical, MRP CMS II analytical.
  - IA and IB variations will be screened based on the variation number.
  - Type II analytical variations will be screened based on the dossier subject mentioned in the application form.

Variations without impact on light AMM

- **Way of proceeding:**
  - These variations will be closed ‘out of the cluster’, which wil result in a faster closing of the dossiers, and a smaller cluster.
  - Simplified way of proceeding in MeSeA: only IP flow.
  - The cycle ‘upload-validation-dossier management-closing’ will be centralised: ‘one dedicated person’will handle the complete cycle.
  - If assessment of the dossier is needed, a second person wil be involved.
  - Each dedicated person will be coached. The coach will perform a quality check of the output of the dedicated person.
  - Training of coach and dedicated person is ongoing.

Variations without impact on light AMM

❖ **Communication to the applicant on dossier output:**

❖Applicant will be informed by automatic mail concerning the possibility of implementation. The actual situation is maintained.

❖The variation is closed internally without external communication to the applicant.

❖At the next update of the light AMM the closed variations will be mentioned on the variation table.

Variations without impact on light AMM

- **Timeline:**
  - Start: 1/06/2009
  - Testperiod of 3 months concerning variations of type IA-IB
  - Testperiod of 6 months concerning variations of type II analytical

Variations without impact on light AMM

❖ **Project within DG POST:**

	Type of dossiers	Adaptation of AMM	Sending AMM
Actual process	IA-IB II ana/clin RQ	yes	yes
Change MAH/batch releaser	IA-IB	yes	yes
Variations without impact light AMM	IA-IB II ana	no	no
Referrals	IB II clin	yes	**Yes** except if only section of SPC changes

Variations without impact on light AMM

Thank you for your attention!

Federal Agency for Medicines and Health Products
(FAMHP)

Backlog Project Implementation Referral, FV Recommendations

Sophie Colyn

19/05/2009

Implementation Referral /FV Recommendations

- Scope
- Links
- Deadlines
- Internal procedure
  - Before submission
  - Proces
    - Full update SPC-PIL
    - No full harmonisation SPC-PIL
    - Dossier not received

Implementation Referral, FV Recommendations

- **Scope :**

New dossiers concerning

- Implementation art30 referral (included in the annex of the decision),
- Implementation art31.1/.2 referrals(included in the annex of the decision),
- Implementation art30 for 'essentially similar'products, (not included in the annex of the decision)
- Implementation of specific "recommendations" .
- National implementation art 29 pediatric regulation 1901/2006/EC

Recommendations :

http://www.hma.eu/23.html

Referrals :

- http://ec.europa.eu/enterprise/pharmaceuticals/register/refh_others.htm

Implementation Referral /FV Recommendations

❖Deadlines:

Implementation Commission Decision:

=>30 Days after publication

10 Days for introduction

=>as soon as possible after publication For Essentially similar's

Implementation of a FV Recommendation:

⇒Total time of 90 days

⇒30 Days for introduction

Implementation Referral /FV Recommendations

- Internal procedure

Before submission:

-FAMHP Letter with clear recommendations:

- dossier requirements
- deadlines for introduction
- text to be implemented in each national language
- Internal contactperson

Proces:

-2 Separate ways

Full update SPC/PIL/Labelling

No full harmonisation SPC/PIL/Labelling

Implementation Referral /FV Recommendations

Proces

1.Full Update SPC and PIL:

Scope

-art. 30 en 31.1 en art29 ped regulation
-Parallel national /MRP implementation “ess.sim”art 30
-MRP variations for recommendation.

=>Full flow with high priority

Cluster

+ pending clinical variations
+variations /renewals that can be finalized

Outcome- Dossier not conform: Letter with neg advice
- Dossier conform: New MAD, SPC and PIL etc

Implementation Referral –FV Recommendation

2.No full harmonisation of SPC and PIL

Scope

-art31.2 referral

-art29 ped regulation

-recommendations

=>Simplified flow: Upload-Adm Check-Closing

No cluster

Outcome

-Dossier not conform: Letter with neg advice

-Dossier conform: Approval Letter which includes the approved section for SPC/PIL

3. Dossier not received:

Letter for Suspension with inactivation of pending dossiers for same MAD

Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

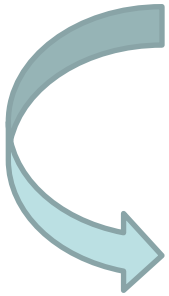
Full evaluation of the SPC, PIL and labelling during the procedure

Christelle Beeckmans

19.05.2008

Objective

- To avoid a second evaluation during the closing phase
- To reduce the time of closing



To examine the SPC, PIL, labelling, mock-up (3 languages) and the logo during the evaluation phase of the new applications, type II clinical variations and renewals

Focus on

- QRD template
- Standard terms of pharmaceutical form,
  route of administration and special precautions for storage
  + correct terminology
- Full naming of the medicinal product
- Similary between the documents about
  - Registration number
  - MAH
  - …

Focus on (2)

- Common leaflets for medicinal products

  with same umbrella name, MAH, active substance, legal basis
- Other modifications noticed out of the topic of the variation
- Blue box requirements
- Granted derogations
- Delivery modus

Sending to the applicant

DCP and MRP

⇨ Via the letter of comments
at different deadlines of the procedure

NAT

⇨ Via a checklist annexed
to the letter of deficiency of the Commission

Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Readability Test – Risk based approach
Change MAH – Mini cluster and documents required
Inactivation – legal basis
Withdrawal letter – Template and contact point

Vanessa Binamé

19/05/2009

READABILITY TEST – Risk based approach

Context

To avoid the creation of a new backlog in the clinical assessments, only the readability test of PL with a potential risk for public health should be evaluate.

For the other, it is the responsability of the MAH to be in accordance with the legislation.

Scope

PL of medicinal products authorised via the national procedure

READABILITY TEST – Risk based approach

Criteria identified until now

SAFETY ISSUES

- Unfavorable pattern of undesirable effects
- Major contraindications and warnings
- Pregnancy risks
- Risk of misuse
- Risk major interactions

READABILITY TEST – Risk based approach

Criteria identified until now

CRITICAL WAY OF USE

- Pediatric drugs
- Pharmacokinetic issues
- Dosing, handling issues
- Need for therapeutic monitoring
- Strategic issues

READABILITY TEST – Risk based approach

Target

Clear, explicit criteria

⇒ Intend to define in a clear and explicit way the conditions were an assessment of the readability test has to be performed with the collaboration of the pharmaceutical industry

Change MAH – mini cluster and documents required

Context

Update of the MA with the new MAH in the legal timeframe

Importance of this change for the industry, the Directorate General Inspection and the Proper Use Division

Mini cluster

The following modifications will be closed together:

Change of MAH, Change of Distributor/Importator, Change of denomination of the medicinal product, change of batch releaser

From 01/01/2010 (new Variation Regulation), these variations could be submitted as one application

Change MAH – mini cluster and documents required

Documentation required for the validation

- Application form
- When applicable: copy of manufacturing authorisation, GMP certificate, formal accreditation of test labortory, declaration by the QP for AS
- FR, NL SPC in word (non protected - track version)
- FR, NL, DE Package leaflet in word (non protected - track version)
- FR, NL, DE outer labelling in word (non protected - track version)
- FR, NL, DE inner labelling in word (non protected - track version)

Change MAH – mini cluster and documents required

- Draft MA (light)
- Draft MA (4pages if applicable)
- Mock up (if your medicinal product is not marketed, a commitment stating that you will provide this mock up via a notification as soon as you have the intention to put the medicinal product on the market)

Approved documents

- AMM
- SPC
- PL
- Labelling

Change MAH – mini cluster and documents required

- Declaration of conformity of translation
- Declaration that no other changes were made to the SPC, PL and labelling that the ones related to the submissions concerned (with a description of these submissions)

The file will be invalid if one of the documents required is missing

Inactivation – Legal Basis

Modification de la loi du 25/03/1964 (article 6 1er)

« Le demandeur ou le titulaire de l'autorisation de mise sur le marché ou de l'enregistrement est tenu de remettre au ministre ou à son délégué, dans le délai fixé par le Roi, tous les documents nécessaires pour clôturer le dossier d'octroi ou de modification de l'autorisation de mise sur le marché ou de l'enregistrement, tels que déterminés par le Roi. Passé ce délai, la demande d'autorisation de mise sur le marché ou d'enregistrement ou de modification est considérée de plein droit comme étant retirée par le demandeur ou le titulaire. Le Roi fixe les conditions, les délais et les modalités nécessaires pour l'application du présent alinéa. ».

L'AR du 14/12/06 doit être modifié pour fixer les modalités

WITHDRAWAL LETTER: Template and Contact Point

Context

All the dossiers regarded as needless by the applicant should be withdrawn. The withdrawals should not concern dossiers introduced on request of the FAMPH or submitted following a European Commission Decision or European recommendation.

Templates drafted by FAMHP should be used. Will be posted on our website.

WITHDRAWAL LETTER: Template and Contact Point

Practical information

One letter by medicinal product group

Takes into account all the dossiers that have to be withdrawn for this specific medicinal product group.

Medicinal product group: all the strengths and pharmaceutical forms of one specific medicinal product

Contact point for this withdrawal letter: Call Center (David Peeters) – a specific mail address will be created

Thank you for your attention!

Programme

- **Plan d'action pour le traitement accéléré des dossiers d'enregistrement et pour remédier au Backlog (AFMPS) : 2ème partie**
  - ✓ **Recommandations pour l'application form (Valérie Lescrainier)**
  - ✓ **Backlog des dossiers en évaluation (y compris les variations du type II) – stratégie de résorption (Greet Musch)**
  - ✓ **Backlog au division pharmacovigilance (y compris les renouvellements quinquennaux) –stratégie de résorption (Wim Penninckx)**
- **Plan d'action pour le traitement accéléré des dossiers d'enregistrement et pour remédier au Backlog (AFMPS) : Q & A**
- **Annonce: nouveau règlement variations: application nationale (Wim Penninckx & Vanessa Binamé) – Q & A**

Actieplan voor het versneld behandelen van registratiedossiers en ter remediëring van de Backlog – 2de deel

Agence **F**édérale des **M**édicaments et des **P**roduits de **S**anté
(AFMPS)

Few tips to fill in correctly a variation application form

Valérie Lescrainier

19.05.2009

1. Administrative data

APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

HUMAN ☐	VETERINARY ☐

☐ NATIONAL AUTHORISATION IN MRP ☐ MRP variation number[1A]: UK/H/685/01-02/AC

If the change is a national administrative change for an MRP product (change of MAH,...), please mention the MRP number followed by AC

☐ COMMUNITY AUTHORISATION EMEA variation number[1B]: EMEA/_/C/___/_/_

☒ NATIONAL AUTHORISATION ONLY

1. Administrative data

Type of Application

- [x] Type IA / AC if administrative change
- [ ] Type IB
- [ ] Type II

1. Administrative data

(Invented)Name:

Mention the current approved name

Active substance(s):

Pharmaceutical form(s) and strength(s) [2]:

MA number(s)[2]:

- If the MA number has not yet been assigned, please mention if there are different primary packaging
- If applicable, please mention the former and the new MA number (976IS421F3 → BE70124)

1. Administrative data

Name and address of MA holder:

Mention the current approved MAH

Name and address of Contact[3]:

Telephone number:

Fax number:

E-mail: = email address where the automatic email (notification of receipt) will be sent

Applicant's reference:

2. IA/IB variations

	Medicinal product registered via national procedure	Medicinal product registered via MRP/DCP
Transfer of MAH	National administrative variation (+ fee)	
Change in the name and/or address of the MAH	National IA n 1 variation	MRP IA n 1 variation
Change of distributor	National administrative variation (+ fee)	
Change in the name and/or address of the distributor (same location)	National administrative variation (no fee)	

2. IA/IB variations

- If MAH A and distributor A → MAH B and distributor B
- If MAH A and distributor B → MAH C and distributor C

The transfer of MAH and the change of distributor have to be submitted together → 1 dossier, 1 application form (2 fees)

<u>For national registered products only:</u>

The variation to change the name/address of MAH (IA VAR) and the administrative variation to change the name of the distributor have to be submitted together (no fee)

2. IA/IB variations

- If MAH A and distributor B

MAH C and distributor D

The transfer of MAH and the change of distributor have to be submitted separately → 2 dossiers

2. IA/IB variations

Reminder:

Consequential changes are not allowed for national IA/IB variations, except for variations IA n 7a) and IA n 8b1):

« replacement or addition of a primary and secundary packaging sites for solid pharmaceutical forms »

3. Clinical variations

If the clinical variation involves changes in the SPC and/or the PIL, it is important to mention exactly which sections of the PIL/SPC are modified and to highlight the changed words in the table “Present/Proposed”.

Avoid, if possible this kind of subject: “Implementation of the latest Company Core Data Sheet” without any information on the changes involved.

3. Clinical variations

It is also important to provide as separate annex an annotated and a clean version of the SPC/PIL.

If the variation is a change in the SPC following a referral or a commission decision, please mention a reference.

3. Clinical variations

If the variation is a change in the SPC following a referral or a commission decision, please mention a reference.

If the variation is a change following evaluation of PSUR , please specify if it is at the demand of the agency.
If yes, please specify the ID nr of the psur.

4. Analytical variations

If the variation is a change in the active substance manufacturer, please mention if there is an ASMF or A CEP.

Don’t forget to provide the QP declaration and the letter of access to the ASMF (if applicable).

Many thanks you for your attention

Federal Agency for Medicines and Health Products (FAMHP)

Action plans for Backlog Management in DG PRE: Drugs for human use

Greet Musch, PhD
Director - General Pre - authorisation

1: General Approach

➢ Inventory of remaining dossiers in division Registration first authorisation (Human) : actions in concertation with DG POST

± 150 dossiers (mainly in closing stage)

Suggestions :

- A to Q limited to max. 3 rounds
- No answers to questions received within proposed timeframe --> negative opnion
- NfG as reminder for adequately documentation requested by the applicant assuring smooth closing of the files

1: General Approach

➢ Review of acceptance criteria for the need/degree of evaluation of different types of dossiers:

-(Co)Rapporteurships , RMS ships

-Readability testing

-Bio-equivalence – Pharmacokinetics

-Chemical-Pharmaceutical review

-Non-Clinical review

1: General Approach

- Monitoring tool for timing the activities of assesors:

  implemented from 04/05/2009

- Pro-active capacity planning for the division of assesors

  (mid – long term):

  - Planning
  - Reporting
  - Cost measurement

2: National dossiers type II variations: clinical evaluation

- Mainly type II variations related to:
  - contra – indications
  - indications / posology

  200 files waiting for initial assessment

- Type II variations: Contra – indications:

  70% of the files

Recrutement of 1 full time equivalent on temporary basis for 1 year

2: National dossiers type II variations: clinical evaluation

- Type II Indications : Posology :
  - Partly outsourcing
  - Partly worksharing within the team of clinical assesors

3: National dossiers Type II variations : analytical evaluation

- Re – allocation of file – management type II variations and file management / evaluations of Type I B variations towards DG Post: from July 2009

- Re – Defining the criteria for evaluation of type II variations
  - Scientific wise
  - Redaction of evaluation reports
  - Based on assessment performed by other recognised member states
  - ± 270 files waiting for initial evaluation

3: National dossiers Type II variations : analytical evaluation

➢Reduced capacity for other assessment tasks:

- Limited (Co) Rapporteurships
- Limited RMS ships
- Further down scaling of assessment / redaction tasks as CMS
- Limited scientific advice support

From June 2009 – December 2009

Thank you for your attention
Suggestions?

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Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Action plan
Backlog Pharmacovigilance

Thierry Roisin
Wim Penninckx

19/05/2009

Scope

- Periodic Safety Update Reports (PSURs)
- Renewals
- EudraVigilance

PSURs *(1/2)*

Decision to evaluate a PSUR based on risk analysis

For new PSURs

Avoids creation new backlog

For older PSURs

Reduces/eliminates existing backlog

System ready for implementation

PSURs *(2/2)*

Criteria used in risk analysis for PSURs *(national MAs)*

- product on the market ?
- date of MA
- date of last PSUR evaluation
- PSUR concerning a medicinal product which should be closely monitored ?
- PSUR submitted via the PSUR work sharing program" ?
- …

Renewals

First (and unique) renewal

Renewal applications "older" medicinal products (backlog)

- *evaluation is considered necessary*

- *decision to evaluate the safety data based on risk analysis*
- *Remedies for procedural obstacles*

Strategy under development;

Ready for implementation in June 2009

EudraVigilance

Yellow cards (paper version) received since 1995

- Temporary resources to validate the data and introduce them in EudraVigilance

CIOMS reports (paper version) received between 1995 and end 2004

- FAGG proposes that MAHs introduce the case reports in EudraVigilance

Actieplan voor het versneld behandelen van registratiedossiers en ter remediëring van de Backlog: Q&A

Annonce: nouveau règlement variations: application nationale

Wim Penninckx

Directeur général DG POST Vergunning AFMPS &

Vanessa Binamé

DG PRE Vergunning AFMPS

Federal **A**gency for **M**edicines and **H**ealth **P**roducts (FAMHP)

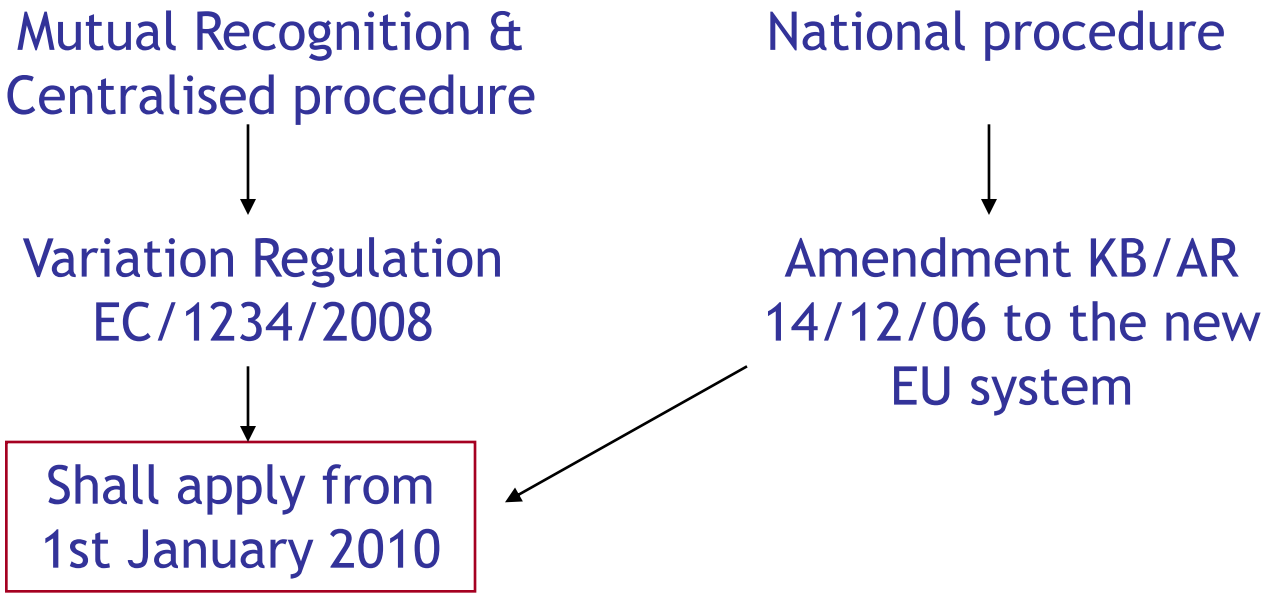
Changes in Variation Regulation

Wim Penninckx, Vanessa Binamé

19/05/2009

Changes in Variations Regulation

- Scope



- Fees

The retribution system will be unchanged.

Each variation of a group will be counted individually.

Changes in Variations Regulation

- ICT (MeseA)

  Necessary changes identified.
  Change requests made.
  Changes implemented in Q4.

- FAGG procedures

  Updated to the new system in Q3/Q4

Further communication in Q3/Q4 of 2009

Clôture

Virginie Peirs
Director Regulatory Affairs FeBelGen