

# Changing and updating the dossier

## Variations, the different types and their respective use

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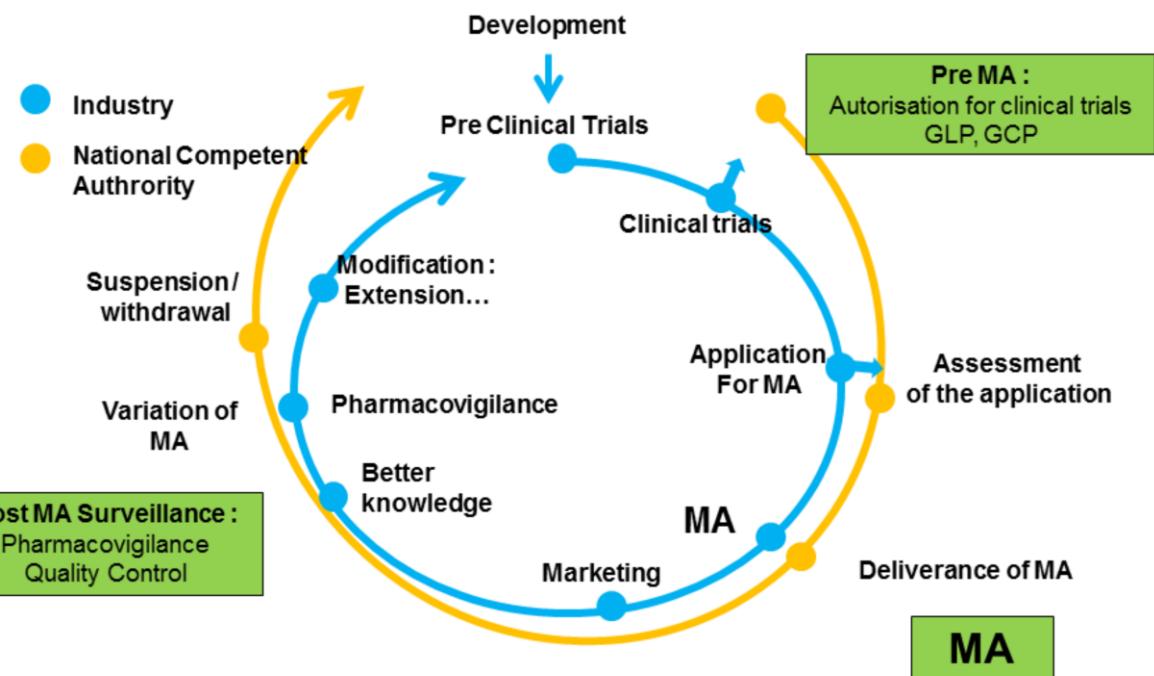
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# Marketing Authorisation Cycle



All products that eventually end up on the market in any given country will go through a lifecycle

From a Company perspective, the development phase is part of the lifecycle of a molecule, product and / or brand. This phase can take up many years and typically sees the attrition of many projects.

Once a company actually starts studies and later assembles a dossier to apply for a Marketing Authorisation, we enter in what we call the MARKETING AUTHORISATION CYCLE

In a first pre MA phase preclinical trials and clinical studies are being conducted. Although limited, the input from Authorities can be important : think about protocol concordance meetings in the US or pre-submission meetings and scientific advice in the European Union.

Once an applicant submits an application, authorities assess the application and grant a license

Now marketing starts, allowing companies to build experience and gain more product knowledge through pharmacovigilance activities.

During this marketing phase, CA can also suspend or withdraw licenses if they feel the benefit risk balance of the product has changed.

Often companies will submit also variations to the dossier, which authorities can accept, or reject. This volume of changes to the MA dossier is the subject of this talk.



## Changing or updating an approved dossier

### ► When?

- Change in manufacturing process
- New data
- New requirements

### ► Why?

- Keep manufacturing compliant and up to standards
- Changes in benefit-risk profile
- New opportunities

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## Changing or updating an approved dossier

- When?
  - Change in manufacturing process
  - New data on safety and/or efficacy
    - Existing indications
    - New indication and/or species
  - New requirements put in place
- Why?
  - Keep manufacturing compliant and up to standards
  - Changes in benefit-risk profile
  - New opportunities



## Why is process needed?

- ▶ Any Changes are variations
- ▶ Variations are subject to approval
- ▶ Legal obligation

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### Why is process needed?

- Any Changes made to a dossier after licensing are variations to the approved dossier
- Variations are subject to approval because they may change the product
  - pharmaceutical quality
  - Safety or efficacy
- Legal obligation in many countries



## Types of changes/updates

- ▶ Part of the dossier
  - Administrative, Quality, Safety, Efficacy
- ▶ Who is asking for a change?
  - Government
  - Applicant
- ▶ Scope of the change
  - No impact
  - Major impact

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### Types of changes/updates

- Part of the dossier
  - Administrative, Quality, Safety, Efficacy
- Who is asking for a change?
  - Government
  - Applicant
- Scope of the change
  - From no impact on product quality, safety or efficacy
  - To major impact on product quality, safety or efficacy



## Typical categories for variations

- ▶ Major variation
  - *Example: new indication, new manufacturing plant, broadening specifications*
- ▶ Minor variation with prior approval
  - *Example: other change in specifications, change in product name*
- ▶ Minor variation without prior approval
  - *Example: tighter specifications, name or address change manufacturer*

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### Typical categories for variations

- Major variation
  - *Example: new indication, new manufacturing plant, broadening specifications*
  - Prior approval required, timeline as for new dossier
  - Dossier rather big
  - Sometimes “complete” extra dossier: EXTENSION (*e.g. new species, new formulation*)
- Minor variation with prior approval
  - *Example: other change in specifications, change in product name*
  - Still prior approval required, often with shorter timeline
  - Dossier usually limited, short timeline
  - Can be “Tell and do”
- Minor variation without prior approval
  - *Example: tighter specifications, name or address change manufacturer*
  - Notifications, “Do and tell”
  - Dossier typically very limited, no “pre-qualifying” timeline
  - Can often be submitted with delay or in annual report



## Challenges

- ▶ Many (quality) variations
  - Workload for authorities (and companies)
    - Work-sharing
  - Grouping of similar variations
    - “group” notifications in 1 variation
    - submit same variation for similar product in one dossier

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### Challenges

- Many (quality) variations
  - Workload for authorities (and companies)
    - Possible work-sharing if the same dossier in several countries
  - Grouping of similar variations
    - Possible to “group” notifications in 1 variation or group in annual report for one product
    - Possible to submit same variation for similar product in one dossier



## Issues and questions

- ▶ Are all applicants keeping their dossiers up to date and are applicants always submitting variations?
- ▶ If not, why not?
- ▶ Do all authorities have same definition of (types of) changes?
- ▶ What is a typical model of types of variation?
- ▶ Does it make a difference if the applicant or the agency are initiating the change request?
- ▶ Are timelines for variation aligned between countries?
- ▶ Can also the assessment of a change be recognized when it was already approved in another country?
- ▶ Would regional collaboration in variation assessment be possible?
- ▶ What needs to change to make that happen (if such direction is endorsed)?
- ▶ Other questions you would like to ask yourself?

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### Notes