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Regulatory Review Process at Swissmedic

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Case Management

- Approx. 200 applications running (administrative to NAS), which must be all in time.
- Different product groups: radiopharmaceuticals, anti-inflammatory medicals (ibuprofen, diclofenac), antidota, antivenoms
- Contact to the applicants (written correspondence, e-mail, telephone)
- Special tasks, work in projects

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The review procedure

Formal Control (30 days)

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First Review (120 days)

↓

Second Review (90 days)

↓

Review after Preliminary Decision/Finalization (90 days)

↓

Review of Texts/Finalization (30 – 90 days)

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Possibilities to safe money and time:

- Orphan Drug Status (free of charge for a new application): according to https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl/zl100_00_001d_mberlaeuterungenzuorphandrugs.pdf.download.pdf/ZL100_00_001e_WL%20Guidance%20document%20Orphan%20Drug.pdf

- Article 13 TPA, if the preparation is not a new active substance NAS (exception: orphan designation): 50% fee reduction

- Quality of the submitted documentation

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Disclaimer

All links shown in this presentation are valid for SOP which are currently in force, based on the current legal situation.

The updated SOP according to the new TPA and Ordinances will be available by September 30th 2018.

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Formal Aspects

- **Regulation for documents:**
  - HD-Guidance document formal requirements
    https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl/zl000_00_001d_wlformaleanforderungen.pdf.download.pdf/zl000_00_001e_wlformalrequirements.pdf

  - Overview of documents to be submitted (an MS Excel sheet)
    https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl/zl000_00_002d_vztabelleeinzureichendeunterlagen.xlsx

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Important documents and general remarks

- Cover Letter: It is the document in which the application is summarized and in which the lack of mandatory documents in the CTD shall be mentioned and justified
- Information for professionals, as pdf and word-file
- Mock-ups of packaging elements instead of word files are highly recommended
- CTD-structure must be followed, especially for modules 2 and 3

Word files vs. Mock-ups

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton

1. NAME OF THE MEDICINAL PRODUCT

Ibuprofen 600 mg film-coated tablet

ibuprofen

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 600 mg of ibuprofen.

3. LIST OF EXCIPIENTS

Contains Lactose

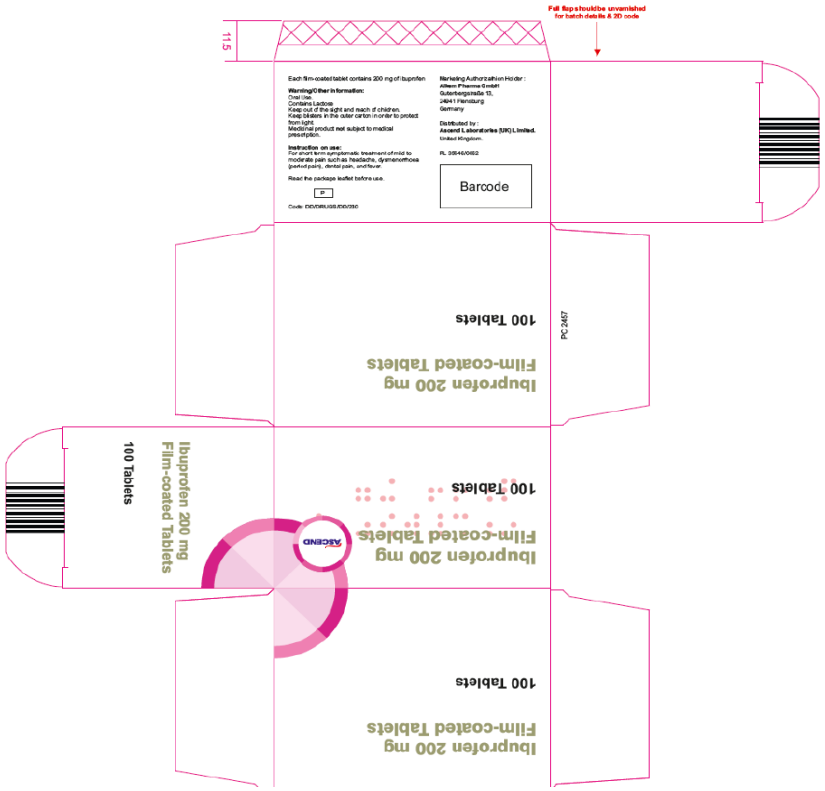
4. PHARMACEUTICAL FORM AND CONTENTS

film-coated tablet

10 film-coated tablet
12 film-coated tablet
20 film-coated tablet
24 film-coated tablet
30 film-coated tablet
48 film-coated tablet
50 film-coated tablet
60 film-coated tablet
84 film-coated tablet
100 film-coated tablet

5. METHOD AND ROUTE (S) OF ADMINISTRATION

Read the package leaflet before use.



Source: MHRA, Public Assessment Report for Alkem Ibuprofen, film coated tablets, Procedure No. UK/H/6559/001-003/DC

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First review, Regulatory

- Preparation of the dossier for the reviewers
- Review of packaging material
  - according to AMZV/OEMéd
  - exceptions must be justified
  - pragmatic solutions for radiopharmaceuticals
- Declaration, from 1.1.2019: full declaration in the information for professionals
- Preparation of the List of Questions package

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Second review and review after preliminary decision, Regulatory

- Finalization of the information for professionals
- Finalization of the packaging elements
- If applicable: information about the applicant protection (10 years for a NAS), which is not a patent protection
- Check of the Public Assessment Reports
- Determination of the fee

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If there are questions prior to a submission of an application:

- **E-mail: andreas.fuerer@swissmedic.ch or urs.eugster@swissmedic.ch**
- **Call Andreas Fürer or Urs Eugster**
- **If answering a question requires more than 1 hour, Swissmedic recommends a scientific advice meeting or a presubmission meeting.**
  The advices are liable to fees (CHF 200.--/hour)

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Scientific advice meeting / Presubmission meeting

- **Three options:**
  - **Face to face meeting**
  - **Telephone conference**
  - **Written answer**

The SOP for a scientific advice/presubmission advice:
https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl/zl105_00_001d_wlfirmenmeetingsimzulassungsverfahrenimbereichzl.pdf.download.pdf/ZL105_00_001e_WL%20Guidance%20document%20Meetings%20for%20applicants%20held%20with%20the%20Authorisation%20sector.pdf

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Thank you for your attention!

Questions?

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