The clinical assessment

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HPRA clinical assessor seconded to EMA

My background

- General practitioner, special interest in heroin addiction treatment and care of refugees
- Joined the Irish medicines agency 14 years ago
- Very diverse workload but focus on medicines being developed for skin diseases
- Currently “on loan” to the EMA for a few years
- Support and train staff and give clinical advice on immunology products
- Other clinical assessors are hospital specialists, clinical pharmacists, or scientists with some relevant clinical background (pharmacology, immunology, oncology etc)

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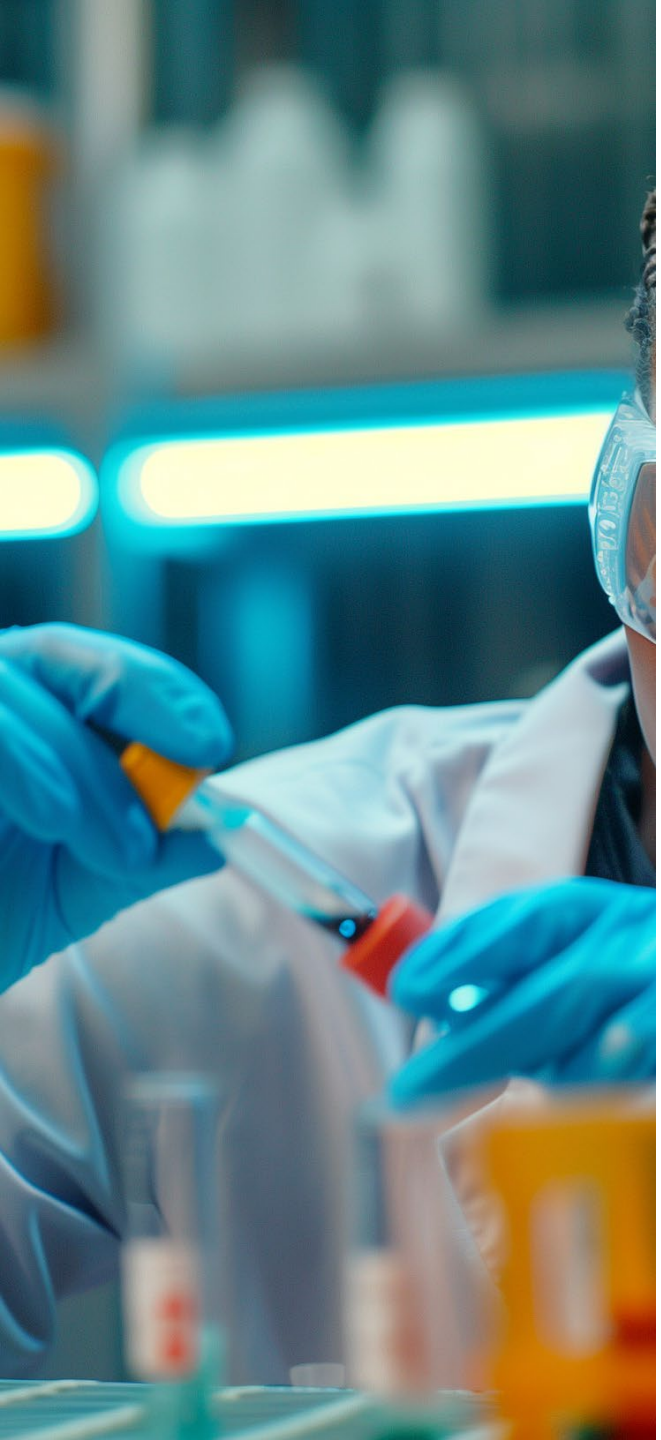

Variety of work at EU and national level

Discreet work projects essentially

- Request by a pharmaceutical company to obtain a license for a medicinal product in an EU member state(s): **Marketing Authorisation Application**
- Request by a pharmaceutical company for advice on their clinical development programme: **Scientific Advice Application**
- Request by a pharmaceutical company or academic group to run a clinical trial of a medicine in an EU member state: **Clinical Trial Application (at national level only)**

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Typical assessment team for a new medicine

Members

- Pharmacokinetics (PK) assessor
- Efficacy & pharmacodynamics assessor
- Safety assessor
- Biostatistician
- Non-clinical (NC) data assessor
- Quality team

Multidisciplinary assessment elements

- PK data can impact safety & efficacy assessment
- Clinical & non-clinical pharmacodynamic data can impact efficacy assessment
- Biostatistician helps interpret the efficacy data
- NC data impacts safety assessment
- Quality issues can impact efficacy and safety

Agree together conclusions on the product and put together a list of questions for the applicant.

Work as part of a multidisciplinary team, across EU countries, with external experts, very collaborative

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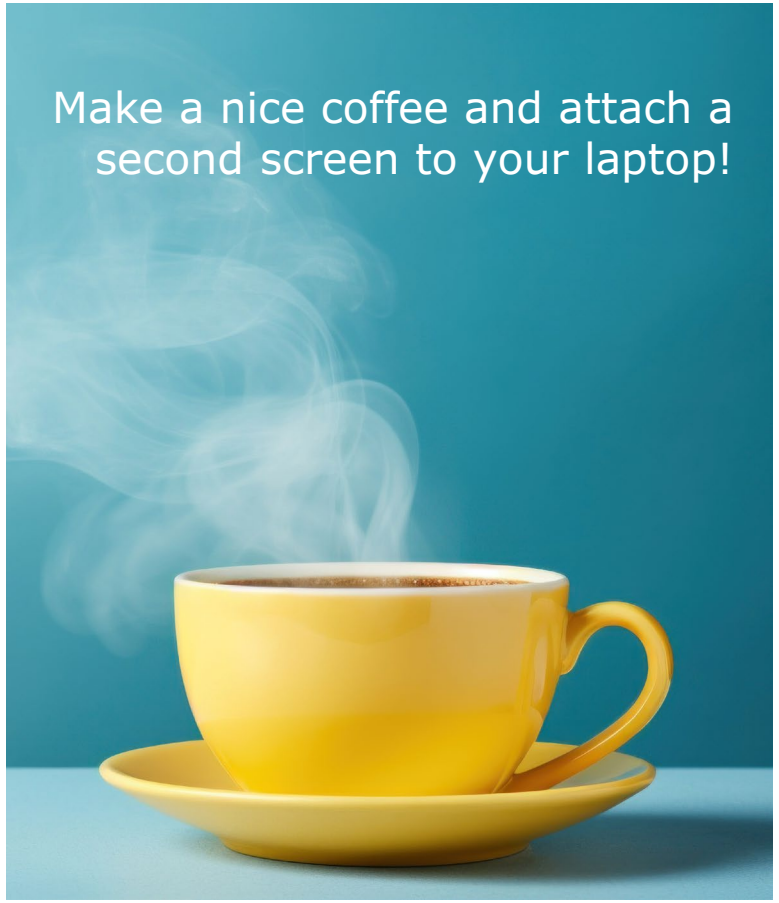
How do I assess, practically?



- Applicants send in a dossier of supporting documents digitally, organised in logical folders

  Introduction and background information

  Applicant's summary and opinion of their data

  Original clinical study data for the product

- Open each folder, take time to digest the content, form an opinion on that content
- Summarise and write those opinions in a standardised assessment template
- Assessment templates contain guidance on what to comment on

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Assessment templates

2.5. Dose justification

Provide a summary of how PK/PD influenced the doses selected throughout the development programme, including, but not limited to, covariate analyses, exposure-response analyses, and simulations to justify the proposed posology. Reference to model-independent (allometric scaling) or model-based (PK and physiologically based PK) approaches based on non-clinical data to determine the appropriate dose in humans, could be made, if relevant.

Please do not duplicate information included later in section 3.2. ; this section should focus on the PK/PD drivers for dose selection.

<Text>

<Invented name>
<Co->Rapporteur Day <60><80> assessment report
Clinical aspects
Rev 03.25 Revamp

Page 33

(Co)-Rapporteur's comments:

Assess if the applicant had a reasonable justification for the proposed posology (as included in section 4.2 of the SmPC) or if there is some uncertainty regarding the selected dose.

Has the proposed posology been sufficiently justified? Including adjustments for specific populations and coadministration of other medicines?

<Text>

Resulting questions:

Any questions can be written here and then transferred into the List of Questions in the CHMP AR/Overview. Mark the question as MO or OC as relevant.

Please focus the questions on issues that, if not addressed, would have a direct impact on the Benefit/Risk evaluation, the SmPC text, the likelihood of inspection, etc. Avoid "nice-to-have" questions.

<None><Text>

2.6. Overall Rapporteur assessment of Clinical Pharmacology

2.6.1. Discussion

The contents of this section should be written so that they can be copied/pasted directly into the CHMP AR/Overview.

One could consider a specific heading relating to the pharmacology and microbiology when the medicinal product under evaluation is anti-infective.

3. Clinical efficacy

Please complete section 3 of this report based on eCTD sections 2.5, 2.7.3. and 5.3.5. Include also completion of template tables as reported below. Use of additional tables for reporting of data is also encouraged in any of the subheadings. Avoid repetition of the same data between text and tables.

Simple copy/paste from the dossier modules 2.5 and 2.7.3 is not acceptable, a degree of simplification is expected. Hence, decide on the minimum detail on individual studies (aim: balanced presentation of "positive" and "negative" findings). Please also include a cross reference to the relevant section of the eCTD.

Distinguish between pivotal trials and supportive trials based on judgement on individual importance (mention all studies, if possible, referring to tabulated summaries).

In each relevant section below, summarise clearly which data are reflected in the proposed SmPC, which are not, and why.

3.1. Clinical development

Please complete the following tabular overview of the relevant clinical studies. Such a table should be aligned with the CTD table 2.7.3.1 (although fewer columns are required).

Table 8: Clinical studies

Study ID	Enrolment status Start date Total enrolment/ enrolment goal	Design Control type	Study & control drugs Dose, route of administration and duration Regimen	Population Main inclusion/ exclusion criteria
<text>				

Only use the text section below if an explanation is needed for the table above.

<Text>

(Co)-Rapporteur's comments:

Briefly describe whether the development plan in principle supports the proposed indication.

<Text>

Resulting questions:

Any questions can be written here and then transferred into the List of Questions in the CHMP AR/Overview. Mark the question as MO or OC as relevant.

Please focus the questions on issues that, if not addressed, would have a direct impact on the Benefit/Risk evaluation, the SmPC text, the likelihood of inspection, etc. Avoid "nice-to-have" questions.

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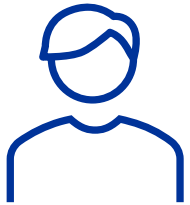
What output is expected from me?

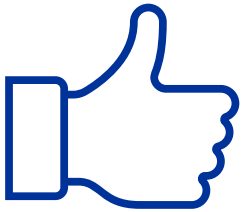
Meet with the applicant before they submit their dossier

Assess the dossier and produce an Assessment Report (AR) to a deadline

Liaise with other EU states to agree a list of questions for the applicant



Log in to the EMA's CHMP plenary meeting when the product is being discussed



Review responses received back from the company

Amend the AR accordingly and give a final opinion to be voted upon

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Typical questions posed

- Did the company study the appropriate category of patients?
- Does the claimed mechanism of action make sense?
- Did the company follow up their subjects for long enough?
- Did the company compare their product to standard of care? Why not?
- Did a lot of trial subjects drop out of the main study? Why?
- Has data for all the key endpoints been presented?
- Did a high proportion of subjects have very serious or severe side effects?
- Did the company study vulnerable populations? If not, why? Is a study planned?
- Does the claimed benefit of the product outweigh the risks? If not, what could the company do?

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Is the work satisfying?

- Involvement in the cutting edge of pharmaceutical science
- Work on the whole life-cycle of a medicine from giving Scientific Advice, to assessing the clinical trial application, to then reviewing the generated data
- Independent assessment, with time to reflect on the data, and update your opinion
- Collaboration with other assessors & experts across the EU network
- Diverse array of products, with variety and complexity
- Bring own experience from a clinical setting to the assessment team
- Still maintain full professional certification and could return to General Practice career at any time

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Heads of Medicines Agencies

Thank you