LOCAL EXPERT ASSESSMENT REPORT TEMPLATE

for

Application for Registration of Pharmaceutical Product Containing New Chemical / Biological Entity (NCE) under special considerations (the "1+ mechanism)

The Local Expert Assessment Report ("the Report") aims to provide a critical review of the benefits and risks of the product for the proposed indication(s) from the local perspective. This template serves as a general guide on the context of the Report for new product registration submitted under the "1+" mechanism.

A. Cover Page

The cover page should include basic information of the product (e.g. product name, active ingredient(s), strength, dose form, pharmacological class, proposed indication(s) and posology) and the expert who is responsible for writing the Report (e.g. name and his/her signature with date).

B. Table of Contents

C. List of Tables/Figures

D. List of Abbreviations

E. Therapeutic context

1. Overview of the disease(s)
2. Global and local epidemiology of the disease(s)
3. International and local treatment paradigms of the disease(s)
    - *A description of the available therapies in the intended population*
    - *Clinical practice guidelines and/or expert consensuses regarding treatment approaches*
    - *A discussion of the unmet medical need of the disease(s) in global and local context*

F. Evaluation and Comments on the Efficacy of the Product

This section should present a critical review of the efficacy data of the product, and explain how the data support the proposed indication(s) and posology

1. Clinical studies
    - *A discussion on the study designs, patient populations, and efficacy results of the pivotal clinical studies and supportive studies (if applicable)*
    - *Comments on the clinical relevance of the magnitude of the observed effects, and any uncertainties and limitations about the efficacy of the product*

- *A discussion on the consistency of results across studies*
- *A discussion on the generalizability of the clinical study results to clinical practice*
- *A discussion on the applicability of overall clinical data to the local patient population*

2. Local clinical data
    - *An assessment of the local clinical data of the product, including a comparison of efficacy results across the local and non-local clinical studies and data*
3. Clinical data in Chinese and/or Asian patient population(s) *(may skip if section 2 is provided)*
    - *An assessment of the clinical data generated from Chinese and/or Asian patient population(s) for extrapolation to the local patient population, considering the ethnic factors relating to the intrinsic and extrinsic characteristics of the populations in accordance with ICH E5 "Ethnic Factors in the Acceptability of Foreign Clinical Data"*
    - *An assessment of such clinical data, including a discussion on the consistency of efficacy results across clinical studies*
4. Post-marketing experience *(if any)*
    - *A discussion of real-world evidence of the product*

G. Evaluation and Comments on the Safety of the Product

This section should present a critical review of the safety data of the product, and explain how the data support the proposed indication(s), posology, and content of package insert.

1. Clinical studies
    - *A review of common and non-serious adverse events, serious adverse events, deaths, and long-term safety outcomes in the pivotal clinical studies and supportive studies (if applicable)*
    - *Comments on severity, frequency, reversibility and tolerability of the major risks of the product*
    - *A discussion on the consistency of results across studies, any uncertainties and limitations on the safety aspects of the product*
    - *Advice on the approaches to prevent, mitigate, manage or monitor adverse events*
    - *A discussion on the applicability of overall clinical data to the local patient population*
2. Local clinical data
    - *An assessment of the local clinical data of the product, including a comparison of safety results across local and non-local clinical studies and data*
3. Clinical data in Chinese and/or Asian patient populations *(may skip if section 2 is provided)*

- *An assessment of the clinical data generated from Chinese and/or Asian patient population(s) for extrapolation to the local patient population, considering the ethnic factors relating to the intrinsic and extrinsic characteristics of the populations in accordance with ICH E5*
- *An assessment of such clinical data, including a discussion on the consistency of safety results across clinical studies*

4. Post-marketing experience *(if any)*
    - *A discussion of any new or different safety issues identified from pharmacovigilance and real-world evidence of the product*

H. Benefits and Risks Conclusions

- *A benefit-risk assessment based on weighing of the benefits and risks of the product*
- *Any uncertainties which may impact on the benefit-risk assessment*

I. Literature References

J. Appendices

1. Curriculum vitae of the expert
    - *With a focus on affiliation(s), fellowship(s), qualification(s) and experience in the therapeutic area(s) relevant to the product*
2. Declaration of interest

Format: The document should be provided as a text searchable Portable Document Format (PDF) file, with page numbers. It is recommended to use Times New Roman, font size 12 and 1.5 line spacing for the Report.

Drug Office

Department of Health

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