<Name of the biosimilar medicinal product>

<Competent Authority (NRA)>

<APPROVED / NOT APPROVED>

PART A - ADMINISTRATIVE INFORMATION		
Entered by:	**Biosimilar Product Information**	
MAH	**Name of the biosimilar medicinal product**	< Invented/Trade name >
MAH	**MAH**	Name and address
NRA	**Authorisation / Licence number**	< local authorisation number >
MAH / NRA	**API manufacturing facilities and batch release site for the finished product** (if applicable)	< Name(s) and address(es) > < Confidential – Not Released >
MAH	**Name of the active substance**	(INN/ Common name/ Local name/ BQ if applicable)
MAH	**Pharmaco-therapeutic group**	e.g. ATC code
MAH	**Substance category**	As described in WHO INN guidance: WHO/EMP/RHT/TSN/2014.1
MAH	**Pharmaceutical form**	Standard Term
MAH	**Quantitative composition**	Strength
MAH	**Route of administration**	Route
MAH	**Packaging/material**	Primary container
MAH	**Package size(s)**	Presentations available
MAH	**Local legal basis**	Legislative Reference (Indicate which regulatory pathway has been used to approve the product)
MAH	**Local biosimilar guidelines**	Reference to applicable guidelines
MAH	**Date of authorisation/licensing of biosimilar**	Approval date for biosimilar
	Reference Biotherapeutic Product (RBP) Information	
MAH	**Name of the RBP**	Trade name of reference biotherapeutic product
MAH	**Authorised indications for RBP**	Indications approved for reference biotherapeutic product in full or summary + English reference
MAH	**Pharmaceutical form**	As detailed in RBP label

MAH	**Quantitative composition**	As detailed in RBP label
MAH	**Route of administration**	As detailed in RBP label
MAH	**Packaging/material**	Primary container
MAH	**Package size(s)**	Presentations available (include as appropriate)
MAH	**Authorisation (Licence) number (of RBP)**	Local (e.g. NCA) code for reference biotherapeutic product
MAH	**Date of authorisation (of RBP)**	Approval date for reference biotherapeutic product
MAH	**Authorisation (Licence) Holder (of RBP)**	Company name of licence holder
MAH	**Source of RBP (or other comparator) for comparability exercise**	Region(s) where reference biotherapeutic product has been acquired in order to perform biosimilarity exercise.
MAH / NRA	**Availability of the RBP assessment report** (language)/**link**	Provide link to public assessment report in local language for reference biotherapeutic product
	Summary of outcomes	
MAH	**Comparability exercise to demonstrate similarity to RBP**	High level summary of data included in comparability exercise for biosimilarity.
NRA	**Availability of full assessment report** (language)/**link**	Provide link to main public assessment report for biosimilar product
MAH	**Indications applied for** (if different to RBP)	Summary of indications requested in biosimilar application
NRA	**Authorised indications for biosimilar**	Indications approved following review – in full or if available in English on NRA website: provide summary and link.

MAH (Marketing Authorisation Holder) or Sponsor
NRA (National Regulatory Authority) i.e. CA (Competent Authority)

PART B - SUBMITTED DATA AND REVIEWER SUMMARY	
Procedure: <Initial Application> <Variation / Supplement> **<Variation number and scope: [Quality / Safety / Efficacy / Risk Management] and description>**	
MAH	**Quality data. Composition of the biosimilar product(s)**
	Provide name of active substance and strength. Provide names (qualitative) of excipients used in formulation.
MAH	**Quality data. State-of-the-art methods**
	Include high level summary of physicochemical test methods and biological activity studies used for characterisation (Tables may be used for clarity).
NRA	**Quality data assessment outcome**
	Provide high level summary review of comparability data. Specify any differences requiring additional assurance and outcome (any differences? If yes, why it was not considered to affect quality, efficacy or safety of the product? i.e. including the underlying scientific assessment).
MAH	**Mechanism of action**
	Describe mechanism of action relevant to indications applied for.
MAH	**Nonclinical data. *In vitro* studies**
	Specify dose used and length of the study.
MAH	**Nonclinical data. *In vivo* studies**
	Specify animal model(s), e.g. dose used and length of the study.
NRA	**Nonclinical data assessment outcome**
	Provide high level summary review of nonclinical data and outcome (any differences? If yes, why it was not considered to affect efficacy or safety of the product? i.e. including the underlying scientific assessment).
	CLINICAL STUDIES **- include relevant study data from the following (not all may be required) which have been included to demonstrate biosimilarity.** • **Pharmacokinetic, PK** • **Pharmacodynamic, PD** • **Efficacy,** • **Safety,** • **Immunogenicity.**
MAH	**Clinical data. PK studies**
	Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the study.
NRA	**Clinical data. PK data assessment outcome**

	Provide high level summary review of PK data and outcome (any differences? If yes, why it was not considered to affect efficacy or safety of the product?).
MAH	**Clinical data. PD studies**
	Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the study.
NRA	**Clinical data. PD data assessment outcome**
	Provide high level summary review of PD data and outcome (any differences? If yes, why it was not considered to affect efficacy or safety of the product?).
MAH	**Clinical data. Efficacy studies**
	Specify study number(s) and summary of design, population, objective and endpoint (e.g. equivalence margins), dose used and length of the study.
NRA	**Clinical data. Efficacy data assessment outcome**
	Provide high level summary review of clinical efficacy data and outcome (No differences should be seen, however, justification may be appropriate for minor differences). Provide summary of scientific evidence leading to decision on extrapolation.
MAH	**Clinical data. Safety/ Immunogenicity studies** (specify population, dose used, length of the study and comparability margins)
	Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the stud(ies).
NRA	**Clinical data. Safety/ Immunogenicity data assessment outcome**
	Provide high level summary review of clinical safety and immunogenicity data and outcome (No differences should be seen, however, justification may be appropriate for minor differences). Safety. ADRs were <not> observed. <The ADRs were equivalent to the ADRs observed with the RBP.> <The ADRs were different from the ADRs observed with the RBP.> Immunogenicity. Antibody formation in < biosimilar product> was considered to be comparable to that in the RBP, using appropriately validated methods.
MAH	**Interchangeability data**
	(If legislation applicable to your Authority allows interchangeability, specify any additional data that has been provided, as appropriate) OR state < No additional data were provided >
MAH	**Additional information about the comparability exercise** — As appropriate, if not previously included.
MAH	**Post-authorization measures**
	Is a risk management plan available? Which Q/ S/ E studies are included?
NRA	**Post-authorization risk measures: assessment outcome.**
	< The risk management plan (or equivalent) was considered to be acceptable. > < No additional risk management activities are foreseen post-approval.>

MAH	**Availability of additional relevant information in the local language/ link**	As required /appropriate

PART C - REVIEWER CONCLUSIONS	
NRA	**Conclusions on biosimilarity, approval**

The data provided by the Applicant were in line with the local legislation and guidelines.
<The data provided by the Applicant were in line with the local legislation, guidelines and international guidelines.>

Quality
The biosimilar manufacturer has developed and validated a process capable of consistently manufacturing a product of appropriate quality, with satisfactory control of impurities. Manufacturing operations are carried out according to cGMP requirements.

The quality attributes of high relevance for clinical safety and efficacy, e.g. physicochemical characteristics and biological activities of < biosimilar product trade name > were comparable to those of the reference biotherapeutic product <trade name >.

Nonclinical
No major differences in nonclinical data were observed for < biosimilar product trade name > compared to the reference biotherapeutic product <trade name > .

Clinical Studies
The PK / PD / efficacy studies to demonstrate biosimilarity conducted in < patient population> provided robust evidence there are no clinically meaningful differences versus the reference biotherapeutic product <trade name >.

Additional data were provided < in another indication> to support biosimilarity / demonstrate interchangeability (this summary report may not include decision in interchangeability).

Safety: The ADRs observed with < biosimilar product trade name > were in the same range as the ADRs observed with the reference biotherapeutic product <trade name >.

Immunogenicity: The proportion of patients who developed anti-drug antibodies (ADA) with < biosimilar product trade name > was generally similar for the reference biotherapeutic product <trade name >.

Extrapolation of indications: Based on the totality of evidence, all indications requested for < biosimilar product trade name > (see Section A, summary of outcomes) were considered to be approvable.
< Due to a lack of assurance concerning <quality / nonclinical / clinical > data, the indication(s) < enter summary of non-approvable indications > were not granted for < biosimilar product trade name >.

Risk Management
The risk management plan (or equivalent) was considered to be acceptable.
< No additional risk management activities are foreseen post-approval.>

Overall Conclusion
Satisfactory assurance of biosimilarity was demonstrated using an appropriate comparability exercise.
<Concerns raised during the review relating to < summarise major issues > were resolved during the procedure.>

The biosimilar product <trade name > was considered approvable.

<< The NCA has determined that the biosimilar product <trade name > was considered to be interchangeable with the reference biotherapeutic product <trade name > . >>