

# Same but different: Basic tools for biosimilar and generic pharmacovigilance writing

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## Abstract

Biosimilars are medicinal products, which are highly similar to an already authorised biological product; generics are identical copies of an already authorised chemical entity. As for any other medicinal product, biosimilars and generics require the writing of pharmacovigilance documents, such as DSURs, RMPs, and PSURs, for submission to health agencies. Due to the nature of biosimilars and generics, the medical writer needs to take into account some specifics while preparing pharmacovigilance documents.

## Introduction

At a first glance, generics and biosimilars seem very much alike: both contain the same active substance (or a version of it) of already existing, authorised medicines (the reference medicinal product, or originator). However, a second look reveals some relevant differences between these two types of medicinal products.

A biosimilar is a biological medicinal product that is very similar to an already authorised biological drug.<sup>1</sup> Biologicals are produced using cells; these can be yeast, bacteria, animal, or plant cells. The characteristics of biologicals are determined by the used organisms and by the manufacturing process. Even minor

changes to this process can have a major impact on efficacy, safety, and tolerability of the product. Due to the inherent complexity of biological molecules (e.g., regarding molecular weight, spatial structure, etc., see Figure 1 opposite), a biosimilar is therefore never identical to its originator and can always only be similar. Biosimilars have come on the stage only a few years ago, and their manufacturing requires highly specialised expertise, staff and equipment, and substantial financial effort (see Figure 1).

All of this is contrary to a generic product, which is a copy of an already authorised chemical entity, the originator. Generics have been available on the market for decades and contain the same qualitative and quantitative composition in active substances and pharmaceutical form as the originator. Apart from proving bioequivalence to the originator, there is usually no requirement for generics to prove efficacy and safety in clinical studies; instead, reference to the originator's data is sufficient.

In summary, the main differences between biosimilars and generics are:

- **Complexity of the molecule:** biological

molecules are much more complex than chemical entities.

- **Manufacturing:** biological molecules are produced in pro- or eukaryotic cells, which is a much more complex and challenging process than a chemical synthesis.
- **Authorisation:** for biosimilars, not only bioequivalence studies need to be performed, but additional comprehensive comparability testing is required (see Figure 2).

All of the above mentioned has an impact on the scope of pharmacovigilance documents, as outlined in the following sections. The most relevant terms used in the context of pharmacovigilance writing for biosimilars and generics are summarised in Table 1 overleaf.

## Pharmacovigilance documents required during a product's life-cycle

Depending upon the developmental stage of a product, various types of pharmacovigilance documents are required by legislation. A product's life-cycle is divided into pre-authorisation, submission and post-authorisation phases (see Figure 3), and each of these phases has its own requirements regarding the pharmacovigilance documents that need to be written and submitted.

### Development phase: development safety update reports (DSURs)

The DSUR is usually the first safety document to be written for a new substance under development, and thus the first occasion where the important identified and potential risks of the compound are defined.<sup>6</sup> In general, this first list of important risks needs to be set up carefully, as at this early stage



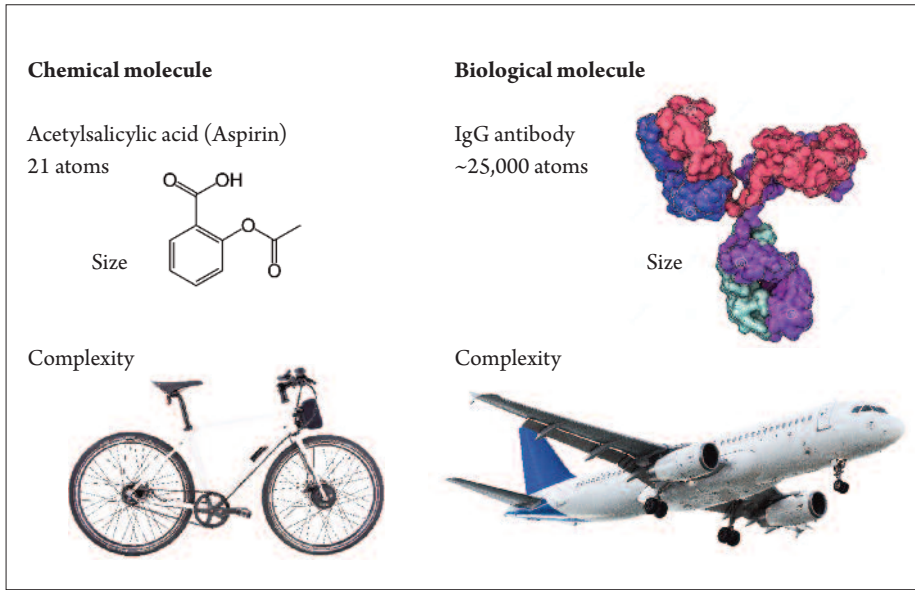


Figure 1. Comparison of biosimilar versus generic. Adopted from Sydow S.<sup>2</sup>

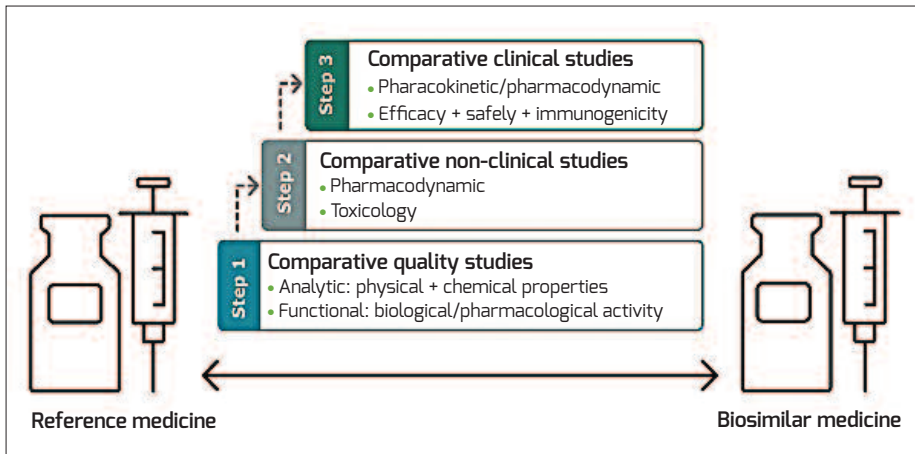


Figure 2. Development programme of biosimilars.

Source: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/biosimilar-medicines-marketing-authorisation> (accessed 15 Feb 2019)

only limited information on a drug's risk profile is available, so that it is difficult to judge whether the inclusion of a risk is justified. In addition, the decisions made for the DSUR impact documents that are required later in the product life-cycle, like the risk management plan (RMP) and the periodic safety update report (PSUR). A careful evaluation is even more important since the

DSUR risk-section is cumulative, i.e., also resolved risks remain in the DSUR's list of safety concerns (albeit an explanation is added in the case of a resolved risk).

For biosimilars and generics, the situation is different. The set of safety concerns is based on that of the originator (lean approach) and, therefore, this first definition of important risks



Figure 3. Overview of pharmacovigilance documents required during a product's life-cycle.

is not necessary. However, some safety concerns of the originator may not apply to the biosimilar or generic product, because they are associated with, for example, a certain component, formulation, route of administration, or specific use of the originator. The lean approach facilitates DSUR writing in terms of this early decision-making on the important risks, and the originator's DSUR or RMP can even be requested and used as a basis for the generic or biosimilar product's DSUR. The downside is that a biosimilar/generic marketing authorisation holder (MAH) may have to deal with important risks in their DSUR (and potentially later on in other safety documents) that they might never find confirmed by their own data due to the limited clinical trial programme.

One aspect of the DSUR remains independent of the originator: the document periodicity. The DSUR development international birthdate (DIBD), which determines the document periodicity, is not harmonised with the DIBD of the originator. This is due to the fact that the DIBD is always determined by the authorisation date of the first clinical trial that is conducted worldwide for a substance, and this also applies to generics or biosimilars. This is true even if only small bioequivalence trials are conducted, which are standard for generic products.

For biosimilars, additionally, extensive comparability testing is required, so that DSURs include more data (from the biosimilar MAH's own clinical trials) than those for generics. Nevertheless, fewer trials and less data are required for a biosimilar than for the originator, which includes data from non-clinical studies and from the clinical development. Biosimilar development programmes require, in general, only phase I and phase III trials. Differences exist not only in the phases and number of trials that need to be conducted to obtain marketing authorisation, but also in the number of trial subjects that need to be included; for biosimilars, trials can usually be smaller than for an originator. Overall, DSURs for generics and biosimilars contain substantially less data than DSURs for the originator.

**Submission phase: risk management plans (RMPs)**

For initial marketing authorisation applications, an RMP is required for all medicinal products.<sup>7</sup>

As mentioned above, as a general rule, generic

**Table 1. Pharmacovigilance writing for biosimilars and generics: basic definitions**

Bioequivalence	Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.
Biological medicinal product	A medicinal product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.
Biosimilar medicinal product	A biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal) in the European Economic Area, and which has shown similarity to the reference product in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise.
Development safety update report	Format and content for periodic reporting on drugs under development.
Generic medicinal product	A medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.
Identified risk	An untoward occurrence for which there is adequate evidence of an association with the medicinal product of interest.
Important identified and important potential risk	An identified risk or potential risk that could have an impact on the risk-benefit balance of the product or have implications for public health.
Missing information	Gaps in knowledge about a medicinal product, related to safety or use in particular patient populations, which could be clinically significant.
Periodic safety update report/Periodic benefit-risk evaluation report	Format and content for providing an evaluation of the risk-benefit balance of a medicinal product for submission by the marketing authorisation holder at defined time points during the post-authorisation phase.
Pharmacovigilance	Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
Potential risk	An untoward occurrence for which there is some basis for suspicion of an association with the medicinal product of interest but where this association has not been confirmed.
Reference medicinal product (also originator medicinal product, innovator medicinal product)	The product that has been authorised first worldwide for marketing. The reference medicinal product is a medicinal product which has been granted a marketing authorisation by a Member State or by the Commission on the basis of a complete dossier, i.e., with the submission of quality, pre-clinical and clinical data and to which the application for marketing authorisation for a similar biological medicinal product refers.
Risk management plan	A detailed description of the risk management system.
Risk management system	A set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions.
Risk-benefit balance	An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks, i.e., any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health.
Safety concern	An important identified risk, important potential risk or missing information.

Sources: GVP Annex I Rev 4,<sup>3</sup> EMA homepage,<sup>4</sup> GaBI online<sup>5</sup>



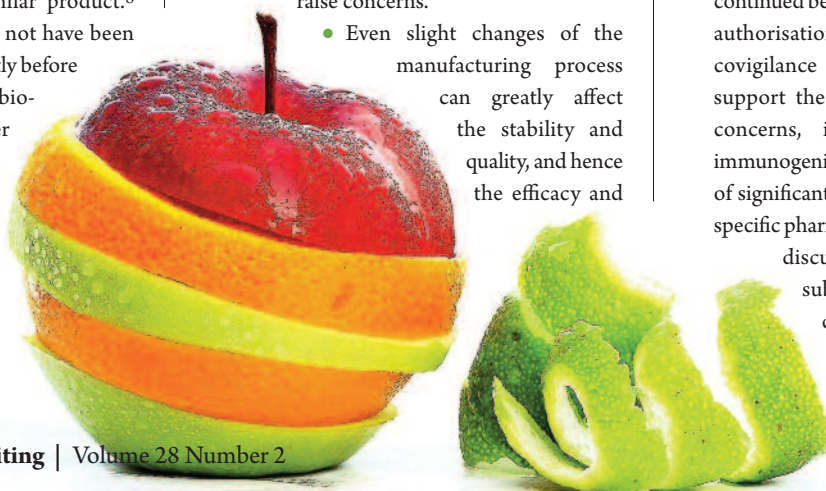
Medical writers need to be aware of specific considerations for biosimilars and generics, while at the same time ensuring pharmacovigilance documents are compliant with the regulatory requirements.

and biosimilar products follow the originators with regard to the list of safety concerns. For originator-specific risks that do not apply to the biosimilar/generic product, it is advisable to consult the health authority (HA) in advance. The RMP of the originator should be requested from the competent HA to align the safety concerns and the related pharmacovigilance and risk minimisation measures. For biosimilars, the comparability exercise could reveal differences in the seriousness and frequency of the risks as compared to the originator: the RMP should discuss these differences and assess the need for additional pharmacovigilance and risk minimisation measures for the biosimilar product.<sup>8</sup> Since the originator's RMP may not have been updated for a longer period, shortly before submission the MAH for biosimilars/generics may consider asking for the most recent originator's RMP or checking the most recent public summaries on the EMA webpage. Although both generic and biosimilar RMPs follow the originators, the

RMP content requirements are different, thus reflecting the different characteristics of these products.

For biosimilars, an almost full RMP is required, with the exception of part II module SI ("Epidemiology of the target population").<sup>7</sup> Due to the nature of biological active substances, some safety concerns are intrinsically related to manufacturing and immunogenicity. These aspects are reflected in the content requirements for the RMP:<sup>8</sup>

- Immunogenicity is not a safety concern *per se* and should not be included as an important potential risk if the data evaluation does not raise concerns.
- Even slight changes of the manufacturing process can greatly affect the stability and quality, and hence the efficacy and



safety, of the active substance. In some cases, the outcome of the comparability test for biosimilars may point towards a deviation from the safety profile of the originator. Significant changes to the manufacturing process trigger an RMP update to provide a specific risk analysis and discuss potential immunogenicity and clinical consequences of significant manufacturing changes.

- A risk might not be associated with the product itself (i.e., with the active substance), but with a component/factor/manufacturing process of the originator, so that the risk's seriousness and frequency for the biosimilar could be unclear as compared to the originator. If there are safety concerns or uncertainties related to the comparability test, the biosimilar RMP should include these and discuss the need for additional pharmacovigilance or risk minimisation measures.
- A specific aspect of pharmacovigilance monitoring for biologicals and biosimilars is the batch traceability. Traceability allows to clearly identify (by name and batch number) a biological product associated with adverse reactions. In case of safety concerns or immunogenicity, it is important to promptly identify the exact product, batch, and supply step. Therefore, the RMP part III ("Pharmacovigilance plan") will describe the clinical settings of use, product's name, batch recording and reporting, and related follow-up and signal detection activities.
- The RMP should include in part III any specific safety monitoring imposed on the originator and discuss its relevance for the biosimilar product.
- Since the pre-authorisation clinical evidence is usually insufficient to identify rare adverse effects, the pharmacovigilance plan of biosimilars must ensure close monitoring of the clinical safety on an ongoing basis and a continued benefit-risk assessment in the post-authorisation phase. Additional pharmacovigilance activities may be needed to support the characterisation of the safety concerns, including the potential for immunogenicity, or batch traceability. In case of significant manufacturing changes, batch-specific pharmacovigilance measures must be discussed in detail at the time of submission of the manufacturing change variation.

- The risk minimisation measures of the originator should be included in the RMP part V (“Risk minimisation measures”) and any deviations should be justified. The RMP part V should describe, in addition, measures planned to improve the biosimilar product’s traceability: for example, the summary of product characteristics (SmPC) and, as applicable, educational material and direct healthcare professional communication, should include a statement recommending that the name and batch number of the product must be recorded in the patient file. Further measures addressing traceability (e.g., sticky or tear-off labels in the product packaging, bar code scanning) are considered risk minimisation measures as well. The RMP for generic products can follow modified requirements, depending on the life-cycle stage and the regulatory settings (see Figure 2).<sup>7</sup>

In general, the safety specification/list of safety concerns is expected to be aligned with that of the originator or other generic products. In case of discrepancies between the approved RMPs of such products, the generic MAH should justify the choice of the safety specification. Exceptionally, if the MAH has more up-to-date data or a certain risk is not associated with the active substance, it is acceptable to propose changes in the list of safety concerns compared with the originator.

The guidance<sup>7</sup> acknowledges three situations in the life-cycle of a generic product that may determine the need for a different format for the RMP part II (“Safety specifications”):

- The originator product has an RMP: as shown in Figure 4, only part II module SVIII (including the list of safety concerns) is required. The generic RMP is aligned with

that of the originator and there is no need to provide new data to determine the list of safety concerns. If the data collected for the generic product point towards removal or new identification of safety concerns compared to the originator, they should be included in part II module SVII.

- The originator product does not have an RMP, but the safety concerns of the substance are published on the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) website: the same approach as in the situation above can be followed.
- The originator product does not have an RMP and the safety concerns of the substance are not published on the CMDh website: the MAH should propose a list of safety concerns based on its own pre-clinical and clinical data, scientific literature, and the originator product’s information. The generic product’s safety concerns have to be characterised and summarised in part II modules SVII and SVIII, respectively.

The RMP parts III and V follow the originator. In case of specific pharmacovigilance or risk minimisation measures being planned or imposed for the generic product, these are included with the appropriate level of detail. If the originator product does not have additional risk minimisation activities, the information provided in the generic RMP part V can be limited to a statement that the safety information in the product information of the generic product is aligned with the originator. If the generic RMP includes additional safety concerns compared to the originator, the risk minimisation activities for these safety concerns should be presented in part V.

The guidance acknowledges the possibility to

adapt the contents of the RMP part VI (“Summary of the RMP”) to the extent indicated by data provided in the other parts of the document.

There can be further scenarios that are not covered by the guidance. In such cases, it is recommended to clarify individual solutions with the responsible HA.

**Post-authorisation phase: periodic safety update reports (PSURs)**

At the time of marketing authorisation, experience with and knowledge about the benefits and risks of a medicinal product are limited. This is even more the case for biosimilar and generic products, as these have a reduced development programme compared to regular medicinal products. In the post-authorisation phase, the PSUR periodically evaluates the benefits and risks of a medicinal product in everyday practice and with regard to long-term use. In the EU, the periodicity and data lock points (DLPs) for PSURs are defined in the European Union Reference Date (EURD) list, which is legally binding. The alignment of periodicity ensures parallel PSUR assessment of all products containing the same active substance.

The objectives and format of this type of periodic report are laid out in Good Pharmacovigilance Practices (GVP) Module VII-Periodic safety update report.<sup>9</sup> The required format and content of PSURs in the EU guidance are based on those described for periodic benefit-risk evaluation reports (PBRERs) in International Council on Harmonisation (ICH)-E2C.<sup>10</sup> To keep the terminology consistent with the one used in the EU, the new PBRER format is still referred to as PSUR.

Post-marketing data normally represent the main data source for a sound evaluation of a product’s benefit-risk balance/profile. However,

Figure 4. Minimum RMP requirements for initial marketing authorisation applications of generic products. Adapted from the GVP Module V (Rev 2), Table V.5<sup>7</sup>

Part I	Part II								Part III	Part IV	Part V	Part VI
	SI	SII	SIII	SIV	SV	SVI	SVII	SVIII				
✓	N/A	N/A	N/A	N/A	N/A	N/A	‡	✓	✓	*	†	✓

- ✓ applicable/relevant
- ‡ Relevant only if originator product does not have an RMP and its safety profile is not published on the CMDh website
- \* Relevant only when a post-authorisation efficacy study was imposed for the originator product
- † Statement of alignment of safety information in product information is sufficient

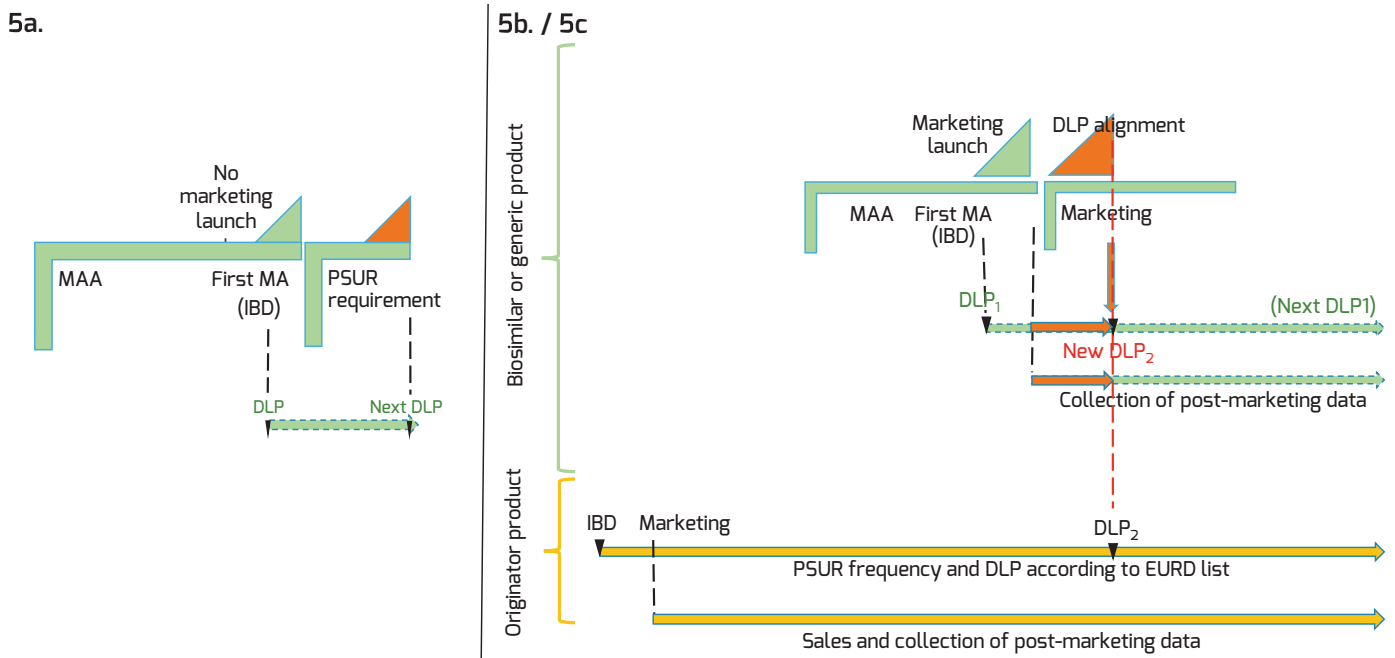


Figure 5. Post-marketing scenarios for generics and biosimilars.

**5a. No post-marketing data available:**

No launch, but PSUR requirement (launch is only possible when the marketing exclusivity rights of the originator product have expired).

**5b. Little post-marketing data available:**

Short marketing phase between launch and PSUR requirement due to the alignment of DLP between generic/biosimilar and originator.

**5c. Post-marketing data available despite short post-marketing time:**

A company holds MA for originator and generic product. One PSUR for all products with the same active substance.

Abbreviations: DLP = data lock point. EURD = European Union Reference Date. IBD = international birth date. MA = marketing authorisation. MAA = marketing authorisation application.

post-marketing data can be available to a different extent, depending on the regulatory circumstances and life-cycle stage of each product. A few examples are given in Figure 5.

There can be several biosimilars for one single originator on the market, owned by different MAHs. It is important that all safety data collected for these biosimilar products can be evaluated in parallel with data from other biosimilars and originators (PSUR EU single assessment procedure for biologicals for centralised procedure).<sup>8</sup> Consequently, the periodicity of a biosimilar PSUR does not start with the biosimilar’s own international birthdate (IBD), as this is usually the case for newly authorised products, but instead the DLPs of the biosimilar PSURs are aligned with the one from the respective originator. The periodicity of the PSUR depends therefore on the originator’s DLP, which is not the case for the DSUR, as outlined in the section above.

With regard to PSUR format and content, a biosimilar follows the same rules as the originator, i.e., there is no separate biosimilars template in place. Nevertheless, there are some specific topics to be considered when writing a biosimilar PSUR, e.g.:

- The extent of biosimilar (non-) clinical data is limited compared to the amount of data that is usually available from a non-biosimilar development programme; this might sometimes require explanation.
- When relevant to signal assessment and interpretation of data, the MAH should include in the PSUR the method of calculation of batch exposure and a summary of the reporting interval batch information. The latter includes batch numbers and size, EU countries and regions of delivery, and, if possible, the number of batches delivered per country/region.
- The available safety information and any relevant differences from the originator should be evaluated in the context of the product’s life-cycle and the batch-specific exposure. Signal evaluation should assess whether the risk (particularly immunogenicity) is specific to a product name/batch or whether the signal applies to the product in general, and/or to all products containing the same active substance.
- If manufacturing changes trigger an RMP update, the evaluation of any associated

- clinical consequences/safety concerns should be supported by batch-specific data and exposure patterns. Depending on the impact of the manufacturing changes, the PSUR cycle of submission may be amended following the updated RMP, meaning that the PSUR submission will no longer be harmonised across biosimilars and related products.<sup>8</sup>
- Given a comparable safety profile between the biosimilar product and its originator, the safety concerns and their related pharmacovigilance activities and risk minimisation measures (e.g., participation in registries, SmPC wording, educational material, etc.) should be aligned with those from the originator and are not derived from the biosimilar’s data and observations (as described in the section on RMPs above). This might need to be explained and consistency with the originator needs to be ensured.
- Any changes to safety concerns, related measures, monitoring topics, SmPC, etc. are usually triggered by activities from the originator. It therefore needs to be ensured that these activities are aligned with the originator.

- Any deviations from the originator’s safety profile based on the biosimilar’s data and signal evaluation should be justified and adequately discussed.

Generic products can be exempted from submitting PSURs under certain circumstances (details are provided in GVP Module VII).<sup>2</sup> If a PSUR is required for a generic (e.g., if this is a condition of the marketing authorisation), the same rules as outlined in GVP Module VII apply;<sup>9,11</sup> there is no separate template for generics. With regard to the content, similar considerations as mentioned above for biosimilars apply for generics, e.g., scope of (non-) clinical data, definition of safety concerns and related measures, alignment with the originator, etc.

**Post-authorisation and beyond**

The writing of the above-mentioned documents continues in the post-authorisation phase. Although the DSUR focusses on the development of a new medicinal product, the requirement for DSUR submission does not cease with the granting of the marketing authorisation. DSURs must be prepared and submitted on an annual basis as long as clinical trials are being conducted for the product. Once the clinical development programme has ended, DSUR writing can be discontinued.

The RMP is part of the submission dossier; however, the RMP is not prepared just once for the purpose of a marketing authorisation application (MAA) but is a living document that will be updated multiple times during the course of the evaluation of the MAA and thereafter. Triggers for RMP updates are plenty, e.g., *ad hoc* due to an agency request, changes in the safety concerns or benefit-risk evaluation, completion of milestones in the pharmacovigilance plan, etc. The RMP needs to be maintained as long as the product is on the market. Post-authorisation RMP updates prompted by safety concerns identified for the originator will be applied to its generic/biosimilar products (and vice versa), unless the trigger of the update is unrelated to the active substance or other common excipients.<sup>8</sup> Since HAs do not inform a biosimilar/generic MAH about RMP updates of the originator, it is advisable to monitor the HA webpage to check for recent updates of public summaries.

PSURs must be written periodically after grating of the MAA according to the schedule

outlined in GVP Module VII,<sup>9</sup> which usually is every six months during the first two years after initial placement on the market, then annually for the following two years, and thereafter every three years (unless required otherwise by the HA). The preparation of PSURs for generics and biosimilars is not a purely regulatory exercise but can lead to a more up-to-date understanding of the product’s safety profile, e.g., if the originator product has a low PSUR frequency requirement. The EMA guidance acknowledges the possibility for MAHs of biosimilar/generic products, as an exception, to propose changes in the list of safety concerns compared to the originator product,<sup>7</sup> where justified by the MAH’s data and evaluations.

**Conclusions**

Biosimilars and generics show some specific characteristics compared to other types of medicinal products. As for any other product, pharmacovigilance documents are required for biosimilars and generics, based on the current legislation, the life-cycle stage of the product, and taking into account the individual characteristics as outlined above. The medical writer needs to be aware of these specific considerations for biosimilars and generics, while at the same time ensuring pharmacovigilance documents to be compliant with the regulatory requirements.

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The opinions expressed in this article are the authors’ own and not necessarily shared by their employer or EMWA.

**Conflicts of interest**

The authors declare no conflicts of interest.

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