



Amgen Australia Pty Ltd
A.B.N. 31 051 057 428

Head Office:
Level 7, 123 Epping Rd
NORTH RYDE NSW 2113
(PO Box 410
NORTH RYDE NSW 1670)
Tel. +61 2 9870 1333
Fax +61 2 9870 1344

Medical Information:1800 803 638

September 7, 2017

Biological Science Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Subject: Department of Health, Therapeutic Goods Administration, Consultation: Nomenclature of Biological Medicines

Dear Sir/Madam,

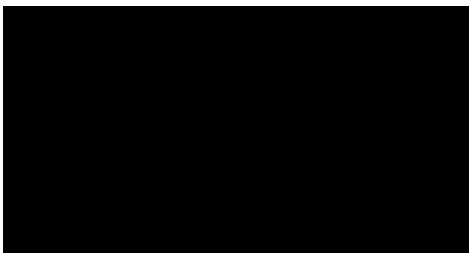
As a developer and manufacturer of both innovative and biosimilar medicines with more than 35 years of experience in the biotechnology industry, Amgen welcomes the opportunity to provide comments on the TGA's consultation on Nomenclature of Biological Medicines (July 2017).

We believe the success of the biosimilar market in Australia hinges upon the confidence of patients and the healthcare community in the quality and safe and effective use of these medicines, which will be supported by scientifically sound principles for approval, accurate prescribing and dispensing, and appropriate use of these products.

In response to the consultation, Amgen expresses its full support for option four, as presented in the consultation. While Amgen also supports any efforts to improve pharmacovigilance (as presented in option two), we believe that this measure alone is not sufficient to deliver on the imperative for the establishment of appropriate traceability to support the accurate attribution of adverse events for biological medicines.

Please direct any questions to [REDACTED], [REDACTED] at [REDACTED] or by email at [REDACTED].

Sincerely,



Amgen Australia/New Zealand

ENCLOSURE: Amgen Comments on: **Consultation: Nomenclature of Biological Medicines**

AMGEN COMMENTS to TGA Consultation on Nomenclature of Biological Medicines

EXECUTIVE SUMMARY

Amgen Australia is the Australian-based affiliate of Amgen Inc., a global biotechnology and pharmaceuticals company based in Thousand Oaks, California, USA. We appreciate the TGA's development and implementation of important policies for biosimilars and welcome the opportunity to offer comments on this consultation on Nomenclature of Biological Medicines. Amgen has a portfolio of both innovative and biosimilar products, and therefore has a unique perspective on the various policy issues arising in the biosimilars market as they apply to both biosimilars and reference products.

Amgen shares the TGA's commitment to patient safety. We believe that there is a need to clearly identify all biological medicines in order to improve pharmacovigilance, which will help build and sustain physician and patient confidence in both innovative and biosimilar medicines. Biosimilar medicines will be safe and effective for the indications of use, but unlike generic drugs, biosimilars are not exact copies of their respective reference products. In addition, biological medicines have the potential to be significantly more immunogenic than traditional small molecule drugs. Their prescribing and dispensing therefore must be accurately and specifically recorded to ensure that adverse events are detected and appropriately attributed.¹ All biological medicines are sensitive to manufacturing, handling, environmental conditions, and other factors that can result in unwanted and unexpected changes in the quality of the product, which could have clinical implications for patients. Additionally, a biosimilar medicine may be licensed for fewer indications and routes of administration than a respective reference product and may also have different delivery systems; these differences create potential risks of medication error.

All biological medicines (originators and biosimilars) must be carefully monitored throughout their lifecycle in order to detect any unexpected changes that impact patients. Effectively distinguishing between multiple manufacturers' versions of a particular biological product will enable all manufacturers to be held accountable for product quality and will help to ensure the optimal medical care of all patients who rely upon these important medicines. Shared Australian Approved Names (AANs)² – a practice which is accepted for generic drugs – are not appropriate for biological medicines. They create an increased and unnecessary risk of ambiguity in product identification and thus an unacceptable risk of delay in time-critical safety notification and research.^{3,4,5} Distinguishable AANs – for example via a distinguishable suffix following a common root or core name – would close a significant gap in pharmacovigilance associated with the current design limitations of many health information technology systems.^{6,7,8,9} Equally important, as stated by the US Food and Drug Administration (FDA), a distinguishable suffix “will provide a consistent, readily available and recognisable mechanism for patients and health care professionals, including providers and pharmacists, to correctly identify these products.”¹⁰

¹ See §II of “Comments of Amgen Inc. on GPhA and Novartis's citizen petitions requesting identical non-proprietary names for biological products and their respective reference products (Docket Nos. FDA-2013-P-1153; FDA-2013-P-1398, respectively)”. Document FDA-2013-P-1153-000, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2013-P-1153-0003>.

² Australian Approved Names are almost always the same as the International Nonproprietary Name (INN).

³ Grampp et al. *Exp. Op. Drug Saf.* 2015; 14(3):349-60.

⁴ Stergiopoulos et al. *T/RS.* 2015; 49(5) 706-716.

⁵ Lietzan EF, Sim LE, Alexander EA. *FDLI's Food and Drug Policy Form—Biosimilar Naming: How do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars?* Washington, DC: Food and Drug Law Institute; 2013.

⁶ Casadevall N et al. *BioDrugs.* 2014;28(5):439-444.

⁷ Grampp et al. “US Health Care Professional Perspectives on Adverse Drug Event Reporting in the Hospital Setting and the Opportunity for Information Technology”. Oral presentation O35 at the 15th annual International Society of Pharmacovigilance meeting (October 28, 2015, Prague Czech Republic). Amgen and the Tufts Center for the Study of Drug Development presented research demonstrating that the majority of surveyed health care providers in hospitals could not reliably retrieve product identifiers for manufacturer, NDC or lot number from their health information technology systems. Program available at: <http://isop2015prague.org/final-programme.htm>.

⁸ Grampp and Felix, *Biodrugs.* 2015; available on line at <http://link.springer.com/article/10.1007/s40259-015-0137-2>.

⁹ See footnote 14 from Amgen's Comments to FDA Proposed Rule: Designation of Official Names and Proper Names for Certain Biological Products, (Docket number FDA-2015-N-0648-0064). Available at <https://www.regulations.gov/document?D=FDA-2015-N-0648-0064>.

¹⁰ Amgen, Comments on FDA Draft Guidance pg. 6, Ln. 231-233. Available at <https://www.regulations.gov/document?D=FDA-2013-D-1543-0166>

Therefore, Amgen expresses its full support for option four, as presented in the consultation. While Amgen also supports other efforts to improve pharmacovigilance (including as presented in option two), we believe that distinguishable nonproprietary names are necessary to deliver on the imperative for the establishment of appropriate traceability to support the accurate attribution of adverse events.

Below are specific comments on the different options outlined in the TGA's consultation paper:

1. The “Status Quo” option

Currently, all biosimilars in Australia share an AAN, which is most typically the International Nonproprietary Name (INN) assigned to the reference product by the WHO INN Expert Group. Prescribing and adverse event reporting that use the AAN do not distinguish between products made by different manufacturers. Although e-prescribing software is expected to eventually support the provision of dispensing information back to the prescribing physician, reporting that relies on the AAN would not allow identification of the specific manufacturer.¹¹ Thus all adverse events would be generalised to the class rather than associated with a particular product/manufacturer.

The pharmacovigilance risk presented by the status quo approach to naming is exacerbated by at least one uptake measure planned in the coming years as a result of the Strategic Agreement signed between the Australian Government and Medicines Australia.¹² This particular initiative involves the pursuit of approaches to ensure that e-prescribing software supports default prescribing by active ingredient name. Thus, the pharmacovigilance efforts of the prescriber could be hindered by the prescribing system if nothing changed.

In both the current and future state, the facilitation of robust pharmacovigilance measures will help ensure the safety and longevity of the biosimilar market. However, the inability to distinguish which specific product was dispensed to a patient due to a shared INN among all manufacturers would dramatically hinder pharmacovigilance. It would hinder the ability to detect potential safety issues associated with a single product or subset of products, and even if a safety issue is detected, valuable time could be lost trying to identify the product responsible.

Pharmacovigilance data associated with two Amgen products currently licensed in Australia demonstrates that the presence or absence of distinguishable AANs either facilitates or hinders accurate pharmacovigilance, respectively.

Using data obtained from the Adverse Event Reports (AERs) reported to the TGA through the Database of Adverse Event Notifications (DAEN) system between 2010 and April 20, 2017, we found that over 36% of all AERs reported for filgrastims did not include information allowing determination of the brand or manufacturer (e.g., they were reported as associated with “filgrastim” only).¹³ This creates ambiguity as to which specific product was associated with the adverse event. These data are also supported by AERs obtained from the WHO Vigibase¹⁴

¹¹Medicines Australia Strategic Agreement. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2017/05/09-May-2017-Strategic-Agreement-with-Commonwealth-Signed.pdf>. Page 14. Last accessed August 23, 2017.

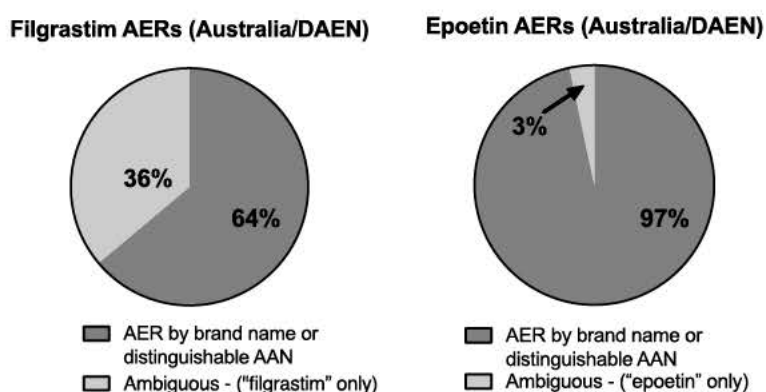
¹²Medicines Australia Strategic Agreement. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2017/05/09-May-2017-Strategic-Agreement-with-Commonwealth-Signed.pdf>. Page 14. Last accessed August 23, 2017.

¹³ Unpublished data obtained by Amgen. Raw data can be provided upon request.

¹⁴ Uppsalla Monitoring Center. Vigibase – WHO global database of individual case safety reports. https://www.who-umc.org/vigibase/vig_base.

reporting system (filtered to list only data from Australia), which suggests that, from 2012-2016, nearly 62% of AERs in the case of filgrastims were ambiguous reports, preventing traceability to a specific brand. Furthermore, in both cases, over 90% of the brand-specific filgrastim AERs were attributed to NEUPOGEN[®], while the Australian market share of that product averaged only 39% over that same time period.¹⁵ These data suggest that shared INNs contribute not only to higher levels of ambiguous reporting, but also to misattribution of adverse events to the reference product.

Conversely, data obtained over that same time period (2012-2016) for epoetins, which possess unique AANs based on glycosylation patterns (epoetin alfa, epoetin beta, etc.), demonstrate that only three percent of AERs were classified as ambiguous (e.g. reported as “epoetin” only). In this case, the use of distinct INNs allowed events to be traced back to specific products, thereby exponentially reducing the incidence of ambiguous reporting.¹⁶



Shared AANs for biological medicines, as they currently exist in Australia, hinder accurate pharmacovigilance, which is not in the best interest of patients, the industry, or the healthcare system. These problems will likely only continue to grow as the number of biological medicines on the market increases. For these reasons, Amgen does not recommend the status quo with respect to the naming of biological medicines.

2. The “Status quo” option with activities that increase public reporting of adverse events

Currently, the TGA’s adverse event reporting system supports reporting using AANs; inclusion of the trade name or batch number is not consistent. As presented in the consultation, option two appears to focus on increasing education to healthcare professionals in order to facilitate reporting of all adverse events by trade name, and perhaps by *mandating* the trade name designation in reporting requirements.

Amgen supports increased education around adverse event reporting and pharmacovigilance. While we could see benefit in mandatory reporting by brand name, data obtained from the European Union (EU) suggests that mandatory brand name reporting alone is not sufficient to ensure optimal pharmacovigilance. For example, when sourcing the WHO VigiBase system for AERs for infliximab products across the EU during 2012-2016, where brand-level reporting is

¹⁵ Unpublished data obtained by Amgen. Raw data can be provided upon request.

¹⁶ Unpublished data obtained by Amgen. Raw data can be provided upon request.

mandated by Good Pharmacovigilance Practices (GVP),¹⁷ we found that after biosimilar infliximabs entered the marketplace, nearly 17% of all reports for infliximab products remain ambiguous as to the specific product involved (e.g., the reports were noted as “infliximab” only, and did not include a specific brand name or other manufacturer-identifying information).¹⁸

In addition, Australian public hospitals use the AAN when prescribing medicines for patients. This is common practice across the public hospital sector in Australia.¹⁹ Public hospitals have systems and processes in place to collect and report adverse drug reactions to the TGA, and current practice is to use the AAN for these adverse event reports.²⁰ Sponsor companies become aware of such reports via public case listing records or the DAEN database but, since cases are not manufacturer specific, have no ability to follow-up on these reports to establish brand name or lot number of the product involved. Currently many Australian hospitals and healthcare facilities utilise paper-based medication administration charts. Without electronic prescribing and dispensing down to the individual patient level, an investigation into an adverse drug reaction report, particularly a retrospective investigation, will not give the reporter the ability to determine the brand involved.

For these reasons, Amgen supports this option of educating the healthcare community to include more product-specific information in adverse event reports, but believes that such measures are not sufficient to promote effective pharmacovigilance.

3. Move towards adopting a barcode system similar to the EU

As stated in the consultation document, the European Commission has mandated in its Falsified Medicines Directive that most medicines supplied in the EU must have a unique two-dimensional (2D) barcode placed on the packaging by 2019.²¹ A similar mandate was adopted in the US through the Drug Supply Chain Security Act (DSCSA).²²

Amgen is aware that the TGA has undergone extensive consultation around the implementation of a 2D barcode system, with planned implementation to occur over the next four years – and a target completion date for 2020. However, the entry of biosimilar medicines to the Australian market highlights the immediate need for the unique identification of biological medicines, particularly biosimilars and their reference products, and further delay in the ability to track and trace multi-source biological medicines should be minimised. The practical reality is that while use of a 2D barcode to supplement pharmacovigilance efforts may indeed facilitate the recording of brand and lot information into a digital form, challenges with the implementation of this approach and downstream effects of this approach may be significant.

For example, in the United States, the DSCSA has already undergone delays in enforcement by FDA due to unforeseen complications throughout the downstream partners of drug

¹⁷ EMA, Good Pharmacovigilance Practices, available at

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp. Last accessed August 23, 2017.

¹⁸ Unpublished data obtained by Amgen. Raw data can be provided upon request.

¹⁹ As noted in the Pharmaceutical Benefits Scheme, pg. 14. Available at <https://www.safetyandquality.gov.au/wp-content/uploads/2016/08/PBS-HMC-User-Guide.pdf>

²⁰ Consultation: Nomenclature of Biological Medicines. Therapeutic Goods Administration, page 7. Available at :

<https://www.tga.gov.au/sites/default/files/consultation-nomenclature-biological-medicines.pdf>

²¹ Medicines Australia Strategic Agreement. Page 14. <https://medicinesaustralia.com.au/policy/strategic-agreement/>. Last accessed August 23, 2017.

²² <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf>. Last accessed August 23, 2017.

manufacturers (e.g. wholesalers, distributors, dispensers, and others that engage in transactions).²³ Recent complications with implementation in the US have suggested that the already-extended deadlines may slip even further due to the incomplete integration of pharmacy systems in their ability to exchange, capture, and maintain tracing information.²⁴ Capture of prescription data from 2D barcodes into patient medical records will require a complex overlay of infrastructure (e.g., scanners at dispensing sites, patient administration locations, medical record software), changes in practice patterns at pharmacies, the development of interactive software between prescribers and pharmacies, and government incentives and mandates to facilitate the full integration. Thus, the 2020 implementation date of 2D barcodes would likely only represent a start for such a complex transition in practice patterns aimed at improving pharmacovigilance. Therefore, while the adoption of 2D barcoding is a step forward in tracking and tracing authentic pharmaceutical products throughout the supply chain (which Amgen fully supports), the actual realisation of the benefits for pharmacovigilance and the penetration into the entire healthcare system will require the adoption of technology that may not be currently widespread in Australia and may take a substantial amount of time and money. This may cause an unnecessary delay in the ability to exercise appropriate pharmacovigilance measures.

Also, while a 2D barcode system may be useful, when used appropriately, to assist in pharmacovigilance measures, it does not assist the patient in identifying the specific product that may have caused an adverse event. In many cases, the primary container package may have been discarded, and 2D barcodes cannot be deciphered by the patient or may not fit on individual containers such as syringes, vials, or packets. Amgen does not support the use of 2D barcodes alone. A more feasible solution may be the incorporation of both 2D barcoding along with suffix identifiers for biological medicines. This would facilitate accurate traceability through the supply chain, but will also facilitate identification of the product by the patient. This is similar to the process taking place in the US with the implementation of 2D barcodes along with the use of suffixes, and is seen as being highly valuable to both patients and manufacturers.

4. Introduce the use of suffixes to the naming of biological medicines

Option four is Amgen's preferred option. As stated above, shared AANs would hinder pharmacovigilance by making it difficult to distinguish between products, especially in cases when prescribing by AAN is encouraged. Therefore, based on the evidence presented above regarding ambiguous adverse event reports, Amgen supports the use of unique suffixes appended to the AANs of biological medicines. In particular, Amgen supports the approach taken by the US FDA by which the names of biological medicines and their biosimilars have a shared core and a distinguishable suffix that "will provide a consistent, readily available and recognisable mechanism for patients and health care professionals, including providers and pharmacists, to correctly identify these products."²⁵ Clear recognition will also foster accurate brand-specific attribution of adverse events, and will facilitate rapid investigation of safety findings associated with a specific product. Consistent with the policy of the US FDA, Amgen believes that this naming convention will help facilitate pharmacovigilance and will help minimise inadvertent substitution at the

²³ Product Identifier Requirements for the Drug Supply Chain Security Act, FDA Draft Guidance. Available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf>

²⁴ Track and Trace and Delay: Pharmacies Get Enforcement Discretion from FDA. Available at <https://pink.pharmamedtechbi.com/PS078650/Track-amp-Trace--And-Delay-Pharmacies-Get-Enforcement-Discretion-From-FDA>

²⁵ Nonproprietary Naming of Biological Products: Guidance for Industry. FDA, January 2017 at p. 6. Accessed at <https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>

pharmacy.²⁶ This approach achieves the balance of clear product identification while enabling stakeholders to recognize associated products. It is a practical tool for facilitating the safe use of biological medicines.

Much of the debate in the US over the use of suffixes has stemmed from the concern that distinguishable suffixes would differentiate biosimilars and would adversely affect market uptake of biosimilars. Real-world evidence fails to support this notion. For instance, biosimilar filgrastim, manufactured by Sandoz, Inc. (under the brand name Zarxio[®] in the US and Zarzio[®] in Europe) has seen substantial levels of uptake in both regions. In Europe, Zarzio[®] bears the same INN as the reference product, filgrastim. In the US, however, Zarxio[®] possesses an FDA-assigned suffix that is associated with the name of the manufacturer: filgrastim-sndz. Data show²⁷ that as recently as July 2017, Zarzio[®] occupied approximately 26% of the filgrastim market share in Europe, while the US product occupied over 33% of the market share; in both regions, it should be noted that the reference product (NEUPOGEN[®]) occupied about 45% of the market. Therefore, as a broad measure, it can be assessed that the presence of a suffix (even an identifiable and meaningful suffix) has little effect on market uptake, and therefore has no adverse effect on the biosimilar itself or the biosimilar market as a whole.

Additionally, Amgen would like to recognise the efforts of the WHO INN Expert Group in their support for the development of the Biological Qualifier (BQ).²⁸ We believe that a globally unified policy under which biological medicines have distinguishable identifiers as part of or associated with their non-proprietary names would ultimately benefit patients, aid in pharmacovigilance, and hold manufacturers accountable for the quality of their products. However, due to the continued complications with the implementation of the BQ system, we believe at this time that it is appropriate to support the global proliferation of an approach similar to the FDA's naming policy. In fact, in the most recent INN Expert Committee Executive Summary, it was noted that the INN Expert Group was "despondent about the future of the BQ", and that "With the US FDA having recently recommended the use of a similar (but distinct) coding scheme for biotherapeutics, it would additionally be an uphill struggle to have the BQ launched and established as a global identifier for biotherapeutics".²⁹ As such, the FDA naming policy is the only currently-implemented naming system for biological medicines that accommodates the introduction of biosimilars and that is directly aimed at supporting pharmacovigilance and accurate reporting of adverse events. It seems reasonable that should the BQ system be implemented in the future, the naming rules proposed by the BQ program could be adapted to align with the criteria set forth in the recent FDA guidance. This collaborative effort would allow a globally-unified suffix to be used and would ease the burden on manufacturers, and facilitate use by the healthcare community, by allowing the same suffix to be used in various regions.

On the possibility of Australia adopting a suffix scheme that differs from FDA's approach, Amgen would recommend against this approach. However, while less optimal than a shared approach with FDA, it is a more sound and patient-centric approach than the utilisation of shared nonproprietary names. However, were an approach identical to that of FDA to be adopted, the TGA and FDA could collaborate on the assignment of suffixes, in much the same way the International Nonproprietary Name is associated with the AAN. In the case that a biological medicine were approved by TGA before it was approved by FDA, the two Agencies could work

²⁶ Nonproprietary Naming of Biological Products: Guidance for Industry. FDA, January 2017 at p. 1. Accessed at <https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>

²⁷ Unpublished data obtained by Amgen. Raw data can be provided upon request.

²⁸ WHO Biological Qualifier Program. http://www.who.int/medicines/services/inn/inn_bio_bq/en/

²⁹ 64th Consultation on International Nonproprietary Names for Pharmaceutical Substances: Executive Summary, July 2017. Available at http://www.who.int/medicines/services/inn/64th_Executive_Summary.pdf?ua=1

together to assign the suffix that would be used by both jurisdictions. As stated above, the proliferation of different naming schemes for biologics would not only complicate matters for regulatory bodies, it would serve as an additional complication and burden on prescribers and manufacturers. Amgen believes that global regulatory authorities would improve global pharmacovigilance by adopting a unified naming scheme.

While support for the use of a distinguishable suffix that is *meaningful* has been very strong among stakeholders that commonly use or encounter drug names (e.g. prescribers, pharmacists, patients, and patient advocates), it is noted that the final FDA guidance on Nonproprietary Naming calls for the use of meaningless suffixes.^{30,31} Amgen continues to support the use of meaningful and memorable suffixes, however, we recognise that the propagation of divergent naming systems could be a burden to industry and various healthcare systems. For this reason, we expressly support the policy of the US FDA in the use of suffixes to distinguish one biological medicine from another.

Applying retrospective suffixes to already-marketed products

Amgen agrees with the US FDA's current approach to the non-proprietary names of already-marketed biologics: all biological medicines should be assigned a distinguishable suffix.

It is also Amgen's position that a retrospective naming policy should allow for voluntary participation by the license holder, in the event a manufacturer may want to proceed with suffix assignment in advance of a requirement by the TGA. However, because changes to the AANs of products already marketed will have wide-ranging ramifications for stakeholders throughout the healthcare ecosystem, the TGA may wish to leverage FDA experience, and adopt an implementation plan that both allows for a transition period and defines a specific date by which all products will have shifted to names with distinguishable suffixes. Sponsor discretion in the procedures involved in implementation of name changes will facilitate the smoothest path forward for all stakeholders. The first products to transition to new names will bear the brunt of the learning curve both in terms of their own changes and the changes that other stakeholders must make and the implications this has for patient access, payment systems, clinical trial protocols, and more. Therefore, the first round of changes should occur over several years and allow for contingencies to accommodate unexpected glitches after the changes are implemented.

Potential considerations for financial impact of retrospective application

Amgen is continuing to assess the potential financial impact of applying suffixes to already-approved products. As noted in our comments to the US FDA Draft Guidance on Naming,³² we are currently examining our own processes and timelines to implement such a name change to a marketed product following the approval of a suffix. Initial assessments suggest that, in order to avoid substantial costs, Amgen would need multiple years to implement this change. Although

³⁰ A 2015 survey conducted by the Alliance for Safe Biologic Medicines of 401 US pharmacists, found that 68% of pharmacists thought that a distinct nonproprietary name should be used for all biological medicines. <https://www.biosimilardevelopment.com/doc/asbm-pharmacist-distinguishable-biologics-transparency-in-labeling-0001>

³¹ Letter to Shaun Donovan, Director of the Office of Management and Budget accessed 08/27/17 at <http://www.pnewswire.com/news-releases/patient-advocates-physicians-pharmacists-unite-to-support-unique-biosimilars-naming-policy-300056526.html>

³² Amgen comments to FDA Draft Guidance on Nonproprietary Naming of Biological Products at p. 11. (Docket number FDA-2013-D-1543-0166). Available at <https://www.regulations.gov/document?D=FDA-2013-D-1543-0166>

concurrent implementation for multiple products is possible, it does increase the time needed for implementation, due to shared personnel and other resources across the product portfolio. Furthermore, an implementation estimate would be highly susceptible to unknown or unforeseen complications that Amgen and other sponsors may face during the changeover process, which might alter the proposed timeframe significantly. It is likely, however, that the TGA could use experiences in the US as a model to more accurately predict the effects on manufacturers and to assign appropriate timelines for implementation.

Amgen recommends against adopting firm deadlines for retrospective implementation of a suffix-based naming convention until the TGA has conducted a working meeting with stakeholders to map out the points within the healthcare ecosystem that will be affected and timelines for implementation are understood. A stakeholder workshop will help the TGA identify and mitigate areas of concern more fully than is likely to result from the comment period without an opportunity for stakeholders to engage in a dialogue. A legal analysis should also be conducted by the TGA to identify areas that may create a risk of misbranding or other legal concerns for which the Agency should establish a clear safe harbor during the transition window.

CONCLUSION

Amgen appreciates the work the TGA has done to develop a scientifically-sound framework for the approval and regulation of biosimilar products. The policies governing the use of these products require careful consideration, as they will have long-term and far reaching implications for patients and the biosimilar industry. In the interest of patient safety and accurate pharmacovigilance, we respectfully request that the TGA adopt the use of distinguishable suffixes in the naming of biological medicines. Amgen remains committed to collaborating with the TGA in developing sound policies that account for scientific realities inherent with biological medicines in order to best serve the interests of patients.