

# What Is a Generic Biopharmaceutical? Biogeneric? Follow-on Protein? Biosimilar? Follow-on Biologic?

## Part 2: Information, Nomenclature, Perceptions, and the Market

by Ronald A. Rader

Part 1 of this three-article series considered various views, paradigms, and definitions of generic biopharmaceuticals (biogenerics), exploring some of the many diverse and conflicting views on this topic (1). Biogenerics are commonly viewed or defined from three different perspectives or combinations thereof: as active agents and finished products through their source, structure, and manufacturing-related aspects (entities, process = product); by their regulatory approvals and applications; and as competing or otherwise similar products in commerce.

Depending on the definition used, there may be no, a few, some, or even hundreds of biogenerics already in the marketplace, and biogenerics may either be a new phenomenon or have been around for hundreds of years, since the earliest biologics.

Similarly, there is no agreement on terms used to refer to such products. Will they be known as (bio)generics, follow-on proteins, (bio)similar, (bio)comparable protein products — or what? Here I'm using *biogenerics*, for lack of a better term, as inclusive of all of these terms and concepts. Confounding the situation, each candidate label and each method for organization and presentation of product information have connotations (objectionable to some), evoke preconceptions, and entail problems that complicate their widespread use.

Here I continue with perspectives on problems involving biopharmaceutical and biogenerics-related information organization and management — prerequisites for the development and dissemination of knowledge. This in turn drives perceptions that largely control products in the marketplace and influence their regulation. As the industry matures and a number of biogenerics start to become available, many related problems will become evident. They include questions about how to define and track unique and distinct products, a difficult task that must be done before defining biogenerics based on relationships between those products; and nomenclature, including the types of names to be used with biogenerics in commerce. For example, is a unique name needed for each product, or will generic names suffice, as for generic drugs? Such information-based factors and related resources will provide the framework for healthcare professional and public perceptions as well as access to these products. Ultimately, everything — controversies, politics, perceptions and the market — depends on how biopharmaceutical and biogeneric information will be defined and handled.

### INFORMATION INFRASTRUCTURE PROBLEMS

Modern biopharmaceuticals, exemplified by recombinant proteins and monoclonal antibodies, were first



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introduced in the 1980s. About 140 are currently approved in the US and European markets (2). Yet there has been negligible development of terminology, taxonomy/classification and nomenclature systems, reference, and other information resources concerning biotechnology and biopharmaceuticals. There is a distinct lack of basic, infrastructure-level information resources concerning biotechnology, particularly when it is viewed as an industrial activity involving products and technologies. Other than resources concerning primary research data (e.g., gene/protein sequences, bioinformatics and other areas of public sector-supported basic research), information resources concerning biotechnology (and biopharmaceuticals) remain fairly primitive. I described this

situation in 1986, and it was also detailed in a 1986 study, *Biotechnology Nomenclature and Information Organization*, by the National Academy of Sciences (3–5).

Two decades later, the situation has changed little, if any. For example, there are a large number of relevant research, medical, regulatory, and company information resources, but there is still just one reference source specializing in biopharmaceutical products (2). There are no comprehensive directories or other resources concerning biotechnologies (e.g., those available for licensing or used in commerce).

Biotechnology and biopharmaceutical products have yet to be integrated into broader chemical and pharmaceutical information science and resources/systems. Because of their complexity, these products defy use of various conventional chemical and pharmaceutical information paradigms, methods, and artifices that work well with drugs and other chemical substances. Other factors result in a scarcity of basic information concerning biopharmaceuticals. From many technical perspectives, such products remain enigmas.

### **WHAT IS A UNIQUE BIOPHARMACEUTICAL?**

As mentioned, biopharmaceutical active agents and products can be described, defined, and considered unique or related/(bio)generic only through multifaceted or holistic consideration of their entity (process = product), regulatory (approval), and commercial aspects. But before you can define relationships and commonalities, you must define what a specific, unique, or distinct biopharmaceutical actually is: What information makes an agent or product unique and distinct from others? And, what entity-, regulatory-, and/or market-based changes in an agent or product require it to be considered a new, different one? How information resources, particularly higher quality resources at the top of the information “pyramid,” handle biopharmaceuticals will provide the framework for how everyone perceives and thinks of such products.

The complexity and diversity of biopharmaceuticals complicates describing them and dealing with related information. Biopharmaceuticals, as with other commercial products, cannot simply be described or defined from a single perspective. In the real world, for most uses, many factors collectively define products, and each factor must be considered. Adequate description of a biopharmaceutical involves lengthy text — useless as a name or identifier. The information needed to describe a biopharmaceutical varies with the type of product, but it generally requires knowledge of its source (e.g., what protein from what organism), structural aspects; the host cells or expression system used for manufacture; the manufacturing process; dosage form/formulation; approval status; and commercial aspects (e.g., manufacturer and marketer).

A significant change from an entity, regulatory, or commercial perspective potentially defines a new, different agent or product. At the simplest or most basic level, a unique biopharmaceutical is a specific finished product, containing a specific active agent, with its own original approval, and manufactured and marketed by a single company. But this simplistic view does not work well in the real world. Agents, products, manufacturing, approvals, companies, and marketing change and evolve; and regulatory approvals often have little relationship to whether products are the same, similar, or new/different.

The same (or similar?) product may be manufactured and/or marketed by different companies, have different dosage forms/formulations, receive different approvals, have different names in different countries, and be sold under the same or a different trade name for the same or different indications.

#### **What Makes Products Different?**

For example, does a product become (must it be considered) a new, different product, if its active agent undergoes a major change — e.g., if the species of host cell line used for manufacture of a recombinant protein is changed? What if the product is largely reformulated — e.g., albumin replaced by a sugar as

protein stabilizer? Does it matter whether such changes result only in a supplemental approval because regulatory agencies somehow consider them to be comparable? And what if such changes are never publicly disclosed (which is very common)? What about the same agent in different formulations (e.g., lyophilized powder and aqueous solution)?

When considering entity-based uniqueness or novelty, should you rely on approvals, which are very inconsistent in this respect (e.g., FDA original versus supplemental biologics approvals) and which often are not reported? Whose approvals (which country’s or countries’) do you go by? Is a product manufactured and marketed by one company the same or different when it is simply relabeled and sold by another company under a different name? Does it matter whether it is sold for the same or a different indication or in the same or different countries?

Some things are fairly clear. For example, products with clearly different active agents are distinct and/or unique. For many purposes, products from different companies, with different trade names and/or for different indications may be judged to be distinct. However, in practice, when dealing with real biopharmaceuticals, you encounter just about every permutation of factors involved. Generally, because of the difficulty, these aspects are often ignored or by necessity loosely applied, much as most current discussions concerning biogenerics fail to define or apply specific criteria. For example, in the only biopharmaceuticals reference, products are considered in the same or separate monographs, with some related similar entries largely redundant and some simply referencing others based on what works to explain the situation (2).

Products that have received original (full) approvals (BLAs or NDAs, for example) can generally be assumed to be unique or distinct from other similar products that have received original approvals. But the FDA and other regulatory approvals often do not correlate well with entity- or commerce-based factors. With

supplemental approvals usually involving the same (or much the same) active agent/product from the same manufacturer, demonstration of comparability and associated supplemental approvals are often accepted as evidence that new versions of products are considered to be the same. However, from an entity-based view, supplemental approvals may require considering the new iteration, variation, or version to be a new, distinct product. In some respects, this involves a biogeneric version(s) of a prior iteration(s).

Biopharmaceuticals present problems similar to naming/identifying other commercial products, with new products and versions perpetually replacing prior ones, and with each iteration requiring identification as products evolve. Biopharmaceuticals have to be defined, named, and tracked much like other commercial products. With software, this often involves using an alpha-numeric, hierarchical classification scheme, e.g., ABC-named product-numbered version x.y.z. Microsoft itself currently sells six "versions" of its Vista operating system (in the United States), each version with its own features, targeted market (comparable to indications), prices, and so on. Then an untold number of OEM versions are customized for specific hardware. And all of these "versions" are frequently updated (comparable to incremental changes in a product and its manufacture).

### **BIOPHARMACEUTICAL NOMENCLATURE**

Like most things, biopharmaceuticals require names. However, due to their complexity, biopharmaceuticals generally defy application of conventional chemical, pharmaceutical, and other information science-based paradigms, methods, and artifices, including nomenclature, that work well with drugs and other chemical substances. Developing nomenclature for biopharmaceuticals, particularly biogenics, will be a contentious issue because it directly affects their marketing, particularly names to be officially adopted (e.g., for filling prescriptions). Product names may be

even more controversial than regulations for biogeneric approvals.

For biopharmaceuticals, conventional chemical/drug nomenclature and registry systems often fail to assign unique or useful generic active agent or product names/identifiers. Registry systems often confound the process by compiling various nomenclature terms in common use, many of which are imprecise and/or inaccurate. Add in trying to have (bio)generic names, ideally, reflecting the nature of biogeneric similarities (e.g., similarities in structure, therapeutic use, or even equivalence/substitution), and the situation gets more chaotic. Further complicating the situation are the transient nature and uncertainties involved with regulated, commercial products, with those products themselves, and with their manufacturing processes, formulations, approvals, trade names, manufacturers/owners, and every other key aspect that potentially defines and differentiates them subject to constant change. And again, much of the most basic entity- and process-related and regulatory information concerning products is never publicly disclosed.

Many types of names and identifiers are applied to pharmaceutical products (6, 7). For biopharmaceuticals, these include

- trade names, including trademarks
- systematic chemical nomenclature, such as that from International Union of Pure and Applied Chemistry (IUPAC) and Chemical Abstracts Service (CAS), primarily designed to index the scientific literature
- nonproprietary (not copyrighted; freely usable) drug nomenclature, such as US adopted names (USANs) assigned by the United States Adopted Names Council used in the United States and International Nonproprietary Names (INNs) assigned by the World Health Organization (UN), used in most other countries
- sequences and sequence database identifiers
- ATCC and other culture collection accession numbers for

biological organisms and materials

- and trivial (common) names.

Each type of name/identifier generally describes biopharmaceuticals from a single perspective and is used for specific purposes, often with little relevance to biopharmaceuticals.

**Names Involve Compromises:** By their nature, but particularly with biopharmaceuticals, names involve compromises. Should they be descriptive (long) or short and useful, for example? Current chemical and drug nomenclature systems have simply not been designed to uniquely identify biopharmaceutical active agents or products, and unless they are redesigned, appear unlikely to work well for biogenics.

Conventional nomenclature systems have been primarily designed and used for drugs and other chemical substances, not biopharmaceuticals. In practice, systematic and other names currently assigned to complex biopharmaceutical agents and products are only indicative or, at best, partially descriptive; such names are rarely uniquely and unambiguously associated with agents and/or products; and they generally describe an agent or a product from a single perspective.

From an entity-based perspective, names rarely are indicative of active agents' structures, source/identity, manufacturing processes, and specifications. Nonproprietary (generic) names, by their very nature, are arbitrary, often being made up to be unique and inherently meaningless (e.g., to minimize mistakes in writing and filling of prescriptions). They often apply to multiple products (based on their active agent being considered similar/identical/generic). They are therefore nonunique and ambiguous.

Systematic chemical nomenclature is a method for linear notation or representation of chemical structure, with trivial/common names adopted and adapted where this fails. Systematic nomenclature simply has not been designed to uniquely identify biopharmaceutical active agents or finished products. Such systems (such as IUPAC and CAS) are primarily oriented to serving the needs of the scientific community, primarily for

indexing chemical substances in the scientific literature, and they avoid differentiating between similar products.

Therefore, different commercial products and their active agent ingredients are assigned the same name, usually based on the active agent. Chemical-based nomenclature also avoids distinctions based on regulatory determinations.

Thus, traditional systematic chemical nomenclatures are of little use as unique identifiers for most biopharmaceutical agents and products. However, this may make them adaptable for naming biogenerics.

Nonproprietary names (not trademark-protected, often called generic names) used in the United States (USANs) are assigned by the USAN Council, affiliated with the US Pharmacopeia (USP). The FDA recognizes/codifies these and has the option of assigning a name itself, if it deems a USAN to be inappropriate. INNs assigned by the World Health Organization (WHO/UN), are generally used in Europe and most other countries worldwide. USAN and INN systems have been developed in the context of their names often being recognized as the official nonproprietary names for drugs, particularly generic drugs, in commerce.

USAN and INN names are assigned to pharmaceutical active agents, then applied to relevant finished drug products, often including those considered bioequivalent and therapeutically identical/substitutable for filling prescriptions. A high priority in designing such names is for them to be unique (relative to other drug names) to avoid prescription mixups, while, ideally, being somewhat descriptive and pronounceable.

Judging products to be identical for all practical purposes (giving them the same name) is often based on products' meeting idealized minimal analytical standards/specifications such as those found in official pharmacopoeias. Standards have been established for only a few of the simplest biopharmaceuticals, e.g., insulin. USANs and INNs are

developed by international committees, and their process of proposing a name can take a year or more. Adapting/adopting these systems for biopharmaceuticals and biogenerics appears unwise, compromising these systems to handle a small subset of pharmaceuticals that simply do not fit well into these frameworks to begin with.

Current chemical and drug nomenclature systems present a number of issues that ill-suit them for biopharmaceuticals. These systems generally fail to differentiate biopharmaceuticals based on aspects other than a single parameter (e.g., primary structure) of their active agent ingredients; they fail to acknowledge that similar products with different manufacturing processes and formulations are different the process = product paradigm); and they do not consider that manufacturers, approvals, trade names, and other factors may define unique products.

As discussed above, any significant change in any of these aspects may warrant considering a biopharmaceutical to be a new, distinct product (or a new version of a product), and a new name may be required. Currently, no system exists for reporting and naming different versions of biopharmaceutical products (exemplified in supplemental approvals). No matter what names are used with biopharmaceuticals, they involve significant compromises.

**Commercial Names Present Problems:** It is often easiest and most useful to name biopharmaceutical agents/products from a commerce or market-based perspective. This primarily involves product trademarks, which often apply only in the context of a particular company, indication, or country, and are subject to changes. For many users and purposes, trademarks are unique, unambiguous, and serve to identify specific biopharmaceuticals and active agents by association with the finished product. The trademark is often the best practical way to identify a specific product.

However, trademarks introduce a number of problems. Besides conveying little or no information about a product, they are all too often

only loosely linked to specific products. Trademarks may actually refer to multiple similar products (be generic) in the same or different countries and/or at different times; they may be restricted to marketing for specific indications; and new trademarks often arbitrarily replace established ones. Legally, trademarks are private property and cannot be systematically used without permission. They legally cannot be used as free-standing names (nouns), and their use is too much like advertising.

#### **New Systems Are Needed:**

Ultimately, biopharmaceuticals will need to be described and assigned different types of names and identifiers from multiple perspectives and for different purposes, including reflecting their entity, regulatory, and/or commercial aspects. Registries will be needed to link and explain the limitations and relationships of various nomenclature terms for each agent and product. This will likely involve use of various taxonomies or classification schemes.

No matter how it is done, complex annotations will be required to convey the nuances and limitations of nomenclature terms and identifiers applied to each agent and product. Both unique and generic names will need to be developed (for different users/uses) for agents and products (for example, a minimum of four names per product) in addition to other preexisting names. Registries compiling the various names will require annotations, which are not included in current systems.

Ideally, the same source should propose nomenclature and maintain a related public registry. Any new system should be capable of handling the diversity of biopharmaceuticals now in development, including biogenerics, gene therapies, and personalized vaccines. Who will do this and how? Currently, these issues are not even being discussed.

#### **BIOGENERICS NOMENCLATURE**

Determining what is a unique/distinct biopharmaceutical agent/product and then assigning a unique name to each

is difficult. But should and how does one assign names indicative of (bio)generic relationships or otherwise applicable to similar or identical agents/products?

The most obvious approach involves using the same names for similar or identical agents and products, ideally indicative of important similarities — source, structure, agent class, activity, and so on — in a way similar to current nonproprietary drug nomenclature systems. Such names may be the ones to be officially adopted for biogenerics, the nonproprietary names officially designated by the FDA and other authorities, particularly for writing and filling of prescriptions.

But should official names be generic (not always unique), following much the same patterns used to assign nonproprietary names to drugs? Or must biopharmaceuticals be treated differently, with each (including biogenerics), even if officially designated as therapeutically equivalent, assigned its own unique (not generic) name?

Biogeneric developers favor nonunique generic names, largely applying the current generic drug nomenclature paradigm to biogenerics, with the same name used for generic and innovator products. This involves using the same nonproprietary name for similar products based on their incorporating a similar/identical active agent. The current choices are USANs and INNs, but those present a number of problems (discussed above). They work well for generic drugs for which active agents can actually be considered identical to each other, including many generic drugs officially approved as therapeutically equivalent/substitutable with their reference product (and each other). Use of generic names for biopharmaceuticals officially considered identical (for practical purposes, if or when this happens) might be appropriate and would clearly facilitate their generic substitution in filling prescriptions.

Generic names facilitate substitution and simplify marketing, providing cost savings. Use of generic names would

allow biogenerics to be marketed (or actually not marketed) like most generic drugs, often simply stocked by suppliers and pharmacies. This allows companies to largely avoid much expensive, product-specific marketing and detailing and allows use of current generic drug distribution systems.

However, use of generic names alone would likely lead to inappropriate substitution and adverse events and make postapproval surveillance very difficult or impossible. This is a major concern in developed countries, whereas many lesser-developed countries may prefer to continue to allow indiscriminate substitution. However, even for biogenerics that receive official designation as equivalent, there may still be safety-related needs to uniquely name each product to support postmarketing surveillance and physician and patient knowledge of what was prescribed.

Current nomenclature and other identifiers applied to biopharmaceuticals are not specific enough to uniquely and unambiguously identify agents or products, and the resulting names are best thought of as generic index terms or descriptors. Selective use or adaptation of those may actually facilitate developing names for biogeneric active agents. In the United States, USAN names for biopharmaceuticals alone (without further specification of a specific product and its dosage form), are not used in filling prescriptions. Thus, besides not being designed for biopharmaceuticals, nonproprietary names assigned to biopharmaceuticals are not used much in US commerce. These factors may facilitate adopting a new system(s).

The situation is more complex and less clear in some European countries and elsewhere. In many such countries, generic names (INNs) alone may be used for filling prescriptions. Many lesser-developed countries encourage substitutions, often with local-manufactured or other biogeneric knock-offs, with their use promoted as being therapeutically substitutable. Such use of generic names as the official names for biogenerics presents a number of potentially serious safety hazards. Even in the United States there are

concerns that using similar names alone for biogenerics could cause safety problems regarding product mix-ups and substitutions, despite prescriptions being specified to their exact product and dosage form/packaging.

Unique agent names (and through them, product names) could be assigned by adapting other inherently generic nomenclature, appending other terms to make names (more) unique yet still descriptive or similar. This could involve artifices such as adding a company name to a (bio)generic name — e.g., aldesleukin/Novartis; or appending an alphanumeric term to each similar product, such as aldesleukin alpha (beta, gamma, or sub<sub>1,2,3</sub> and so on). However, such similar names may be conducive to mixups in writing, filling, and tracking prescriptions; and using company names (which, the manufacturer or marketer?) would be too much like advertising.

#### **WHAT NEEDS TO BE DONE**

Unique and (bio)generic names for both finished products and active ingredients are likely to be required for biopharmaceuticals. Thus, four nonproprietary names should be available for selective use with each marketed product. And any nomenclature and registry system will need to track relevant changes in products as they evolve, including assigning new names/identifiers to different iterations/versions. This will involve tracking changes that effectively redefine each product as a new/different product or iteration/variation/version, including relevant changes in formulation, manufacturing processes and companies, marketing company, therapeutic equivalence, and so on. This will be confounded by the predominant corporate culture of secrecy plaguing the industry; and similarly, by the FDA's and other regulators' timidity in disclosing even basic nonproprietary/nonenabling information about approved products.

Current nomenclature systems work well enough for what they have been designed for: chemicals in the published literature and drugs (not

biopharmaceuticals), including generic drugs. These current systems should not be compromised or “jerry-rigged” to accommodate biopharmaceuticals and biogenerics.

Any new biopharmaceutical nomenclature system should start from scratch. This would include developing working definitions for criteria regarding the information needed to uniquely define unique or distinct biopharmaceuticals; what relationships (information) define similar or generically related biopharmaceuticals; and proposing various types of names for specific agents/products. These should include unique and generic names for both active agents and products, and, perhaps, other names for other purposes, including common/public use. Others should be free to propose names, and everyone — regulatory agencies, companies, formularies, and authors — should be free to adopt (or ignore) these as they see fit.

With Congress expected to get around to passing some type of new law enabling generic biologics approvals (abbreviated filings) in this or next year, the time to start is now. Nomenclature issues ultimately involve balancing the needs of convenience and economics against precision and safety. Ultimately, regulatory agencies decide the name(s) to be used in commerce. In the United States, this means that Congress and agency bureaucrats may be the ones who decide this issue.

Ideally, nomenclature efforts would be industry based and funded, broadly including innovator and biogeneric companies as well as others with vested interests, and not government-based. The organization involved should be small, adaptable, agile, and responsive (quick turnaround), providing both unique and generic names that will satisfy both innovator and biogeneric companies.

A useful model is the *International Cosmetic Ingredient Dictionary and Handbook (the CTFD Dictionary)* developed and primarily sponsored by the main US cosmetics trade association, with the names provided recognized by the FDA as the authority for cosmetic product ingredient labeling (8). This entirely industry-based effort

has largely enabled cosmetics to avoid FDA regulation (with cosmetics needing only to be properly labeled, requiring no specific requirements for premarket testing or approvals).

### PERCEPTIONS AND THE MARKET

Most everything concerning biopharmaceutical information either does not yet exist or is in a primitive state. With biogenerics, most everything important is relative (literally). So everything is in play, the field is a vacuum, anyone can get involved, and whatever useful is proposed or developed first may end up in a strong or dominant position. This includes influencing the development of regulatory regimes.

Information-based and nomenclature issues are likely to be very controversial, perhaps, even more so than the regulations for biogenerics (abbreviated testing and product therapeutic equivalence). For example, key questions include the following.

- Five or 10 years from now, when you go to fill a prescription for a recombinant protein product, will you ask for or be asked whether you prefer a (bio)generic, (bio)similar, follow-on, copy, knock-off, or whatever term for a biogeneric (and one that is similar or equivalent)?

- What name will be used for the prescription, and what name will you use?

- How many will even have a basic understanding of the implications of these labels and names, and where will they learn this from?

- What types of official or other names will the medical community and public use for biogeneric products, and what will be used for marketing?

- How and who will educate professionals and consumers on these issues?

- How can there be transparency and public confidence in biopharmaceuticals, particularly biogenerics, when so much of the most basic product information, e.g., concerning manufacturing, including that relevant to judging safety and uniqueness/similarities, is not disclosed?

- How will official nonproprietary

names be assigned for writing and filling prescriptions? Will they be generic, similar, and/or unique for each product?

- What information, if any, should names for biogenerics convey?

- Will consumers and healthcare professionals think of biogenerics as high-tech products, each receiving the gold standard FDA approval, or will they be perceived as copy-cats, knock-offs, and cheap copies, with second-class approvals and best avoided (as many perceive generic drugs)?

- Will innovators subtly or not denigrate biogenerics, e.g., by promoting “process = product” and related safety concerns to professional communities, or sponsoring “educational” campaigns that biogenerics (or whatever they are called) are not really generics?

The official names to be used for specific biogenerics (and innovator biopharmaceuticals) will directly affect how everyone refers to them, which drives perceptions, which in turn governs marketing. Whether unique or generic names for biogenerics are used will greatly affect their marketing and safety monitoring. The nomenclature (names) by which biogeneric products are known will largely affect whether they respected and considered as safe and effective as the branded products. Official adoption of unique names for biogenerics would favor safety, allow innovators to retain considerable marketing advantage, and put biogenerics at a significant disadvantage, even though generics offer cost savings and convenience.

The biopharmaceutical industry's information-based problems are becoming particularly evident in the context of biogenerics. The industry is finally starting to reach maturity. Information resources and the public knowledge derived from them must be able to rationally handle the diversity of biopharmaceuticals (and biogenerics). New paradigms, terminology, taxonomy, and nomenclature systems will be needed for biopharmaceuticals, particularly ones that include biogenerics. This industry maturation will be painful, requiring industry and regulators to define products and their

## LAUNCHING THE US BIOPHARMACOPEIA PROJECT

Who will develop biopharmaceutical and biogeneric information paradigms, terminology, product names, and related information resources? If left to politicians (Congress) and bureaucrats (FDA), the results will be relevant only within specific regulatory contexts, leaving the scientific and medical communities, media, and public without a common basis for communication. To date, other than posturing and lobbying, organizations that should be involved have avoided these issues.

To help resolve this situation, the *US Biopharmacoepia Registry of Biopharmaceutical Products* ([www.biopharmacoepia.com](http://www.biopharmacoepia.com)) will develop new information paradigms, terminology, nomenclature, and public information resources for biopharmaceuticals, including biogenerics. This is proposed as an industry-based and -funded effort to provide a functional information infrastructure and foundation for how to think of, define, classify, and name biopharmaceuticals, including biogenerics.

This project will develop needed terminology and criteria suitable for describing products' unique and related aspects; propose both unique and (bio)generic names for active agents and finished products (for selective adoption by regulatory agencies, formularies, reference sources, etc.); and provide this information at a public registry web site. All interested are invited to participate in this important project and join its advisory committee. Sponsors (funding) are also needed. Contact Ron Rader at [email@biopharmacoepia.com](mailto:email@biopharmacoepia.com) or 301-424-0255. —**Ron Rader**

relationships and develop related information resources and educational programs.

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