INN Working Doc. 13.327
January 2013
Distr.: PUBLIC
ENGLISH ONLY

Discussion on Nomenclature for Cell Therapy Products and Proposal for Biosimilars

15 October 2012

Programme on International Nonproprietary Names (INN)

Quality Assurance and Safety: Medicines (QSM)
Essential Medicines and Pharmaceutical Policies (EMP)
World Health Organization, Geneva

© World Health Organization 2013

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Discussion on Cell Therapy Products and Proposal for Biosimilars
15 October 2012
Room M-605

Chair: Dr Kevin Grant
Rapporteur: Dr James Robertson

Monday, 15 October 2012

09h00 – 09h30	**Welcome and opening remarks** • Dr Kees de Joncheere. Director, EMP • Dr Raffaella Balocco Mattavelli, Manager of the INN Programme
09h30 – 09h45	**Current INN policy on biological products** • Professor Derek Calam
09h45 – 10h00	**Research and development of cell therapy products and current DRAs policy on nomenclature for cell therapy products** • Dr Kevin Grant, Therapeutic Goods Administration, Australia (TGA)
10h00 - 10h30	***Coffee/tea break***
10h30 – 12h30	**Research and development of cell therapy products and current DRAs policy on nomenclature for cell therapy products (Cont.)** • Professor Dr Zhongping Guo, Chinese Pharmacopoeia Commission, China • Dr Klara Tiitso, European Medicines Agency, United Kingdom (EMA) • Dr Ralf Sanzenbacher, Paul Ehrlich Institute, Germany • Dr Nana Kawasaki, National Institute of Health Science, Japan (NIHS) • Dr Kimberly Benton, Food and Drug Administration, USA (FDA)
12h30 – 13h00	**Discussion:** • Challenges in naming cell therapy products • Nomenclature scheme for cell therapy products? • Recommendataions
13h00 - 14h00	***Lunch break***
14h00 – 15h00	**Cont.** • Recommendataions

Discussion on Cell therapy and Proposal for Biosimilars
15 October 2012
Room M-605

15h00 – 15h15	***Coffee/tea break***
15h15 – 16h00	**Proposal for INN for Biosimilars** (Dr Kevin Grant, TGA)
16h00	**Closure of meeting (Chair)**

List of participants on Cell Therapy Products and Proposal for Biosimilars

INN EXPERT GROUP

- **Professor Derek Calam** — Chair, INN Expert Group, Pewsey, United Kingdom
- **Dr Kevin Grant** — Therapeutic Goods Administration, Woden ACT, Australia
- **Professor Marie-Paule Lefranc** — Institut Universitaire de France, Montpellier, France
- **Dr James Robertson** — National Institute for Biological Standards (NIBSC), Potters Bar, United Kingdom
- **Mrs Stephanie Shubat** — United States Adopted Name (USAN) Program, Chicago, USA
- **Professor Witold Wieniawski** — Polish Pharmaceutical Society, Warsaw, Poland

SPECIAL ADVISERS ON BIOLOGICALS

- **Dr Nana Kawasaki** — National Institute of Health Science (NIHS), Tokyo, Japan
- **Dr Klara Tiitso** — European Medicines Agency London, United Kingdom
- **Dr Robin Thorpe** — National Institute for Biological Standards and Control (NIBSC), Potters Bar, United Kingdom
- **Dr Karin Weisser** — Paul-Ehrlich-Institut (PEI), Langen, Germany

REPRESENTATIVES FROM SPECIALIZED AGENCIES AND RELATED ORGANIZATIONS

- **Dr Zhongping Guo** — Chinese Pharmacopoeia - Commission, Nomenclature of Biologicals, Beijing, People's Republic of China
- **Dr Kimberly Benton** — US Food and Drug Administration (US FDA), Office of Cellular, Tissue, and Gene Therapies CBER/FDA, Rockville, USA

- **Dr David Lewis** — US Food and Drug Administration (US FDA), Center for Drug Evaluation and Research (CDER), Silver Spring, USA
- **Dr Ralf Sanzenbacher** — Tissue Engineering and Somatic Cell Therapy Medical
  - Products, Paul-Ehrlich Institute, Langen, Germany

WHO SECRETARIAT

Department of Essential Medicines and Health Products (EMP)

- **Dr Kees de Joncheere** — Director, EMP
- **Dr Lembit Rägo** — Coordinator, Quality Assurance & Safety: Medicines (QSM)
- **Dr Raffaella Balocco Mattavelli** — Manager of the INN Programme (QSM) and Secretary of the INN Expert Group
- **Dr Ji-Cui Dong** — Technical Officer, INN Programme (QSM)
- **Dr Sophie Lasseur** — Technical Officer, INN Programme (QSM)

Discussion on Cell Therapy Products and Proposal for Biosimilars

15 October 2012

The Chair, **Dr Kevin Grant**, Therapeutic Goods Agency, Australia, opened the meeting and gave the floor to Mr Kees de Joncheere, the new director of the Essential Medicines & Pharmaceutical Policies department.

Mr de Joncheere welcomed the participants to this special pre-meeting of the 55th INN Consultation. He expressed his gratitude to everyone for their presence as it is important that these critical issues are discussed, and wished the participants a fruitful and productive meeting.

Dr Raffaella Balocco-Mattavelli (INN Programme Manager) similarly welcomed all participants to this pre-meeting of the 55th INN Consultation, especially those who are not members of the INN Expert Group. There has previously been internal discussion amongst the Experts on a naming scheme for cell therapy products, which concluded that it was not needed. However, the INN Programme is repeatedly being approached about it, with requests for a naming scheme, and so relevant experts, both cell therapy and INN, have been brought together for this discussion. If there is a global need for a scheme, then WHO should contribute on this level. Also on the agenda will be a presentation and discussion on biosimilars by Dr Grant. Governments are tackling these in different ways and more work on INN for biosimilars is needed by the WHO.

An introduction to the current INN policy for biological products was provided by **Prof. Derek Calam** (Chair, INN Committee). The INN programme was established by WHO in 1953 to devise non-proprietary names at a global level which can be used by anybody to identify a substance for clinical therapeutic use. Ideally this was to be a single word, translated into many languages. Principles were established including avoiding names that directly indicate their therapeutic use, and avoiding single letters and numerals. To date almost 9000 INN have been assigned Vaccines are a special group dealt with by a separate WHO department and generally are not included in the INN scheme. In creating an INN, attempts are made to group together substances that have a similar therapeutic use or structure, to provide them with a single word name, in two or three parts consisting of a random prefix, a suffix which indicates a group of substances (a stem) and possibly an infix (or sub-stem).

In the past ten years there has been a series of specialised meetings on biological substances and currently 30-40% of submissions are for biologicals. INN for monoclonal antibodies (mAbs), a particular class of biologicals, have a *–mab* stem (suffix), two substems (one for the origin/type of mAb, and one for the target, plus a unique prefix, and more than 200 mAb INN have been assigned. INN for gene therapy products, another class of biological, comprises a two word name, each with a specific construction with the first word being assigned to the gene whilst the second word is for the vector. Both mAbs and gene therapy products are good examples with precedents that could be used for a globally acceptable solution for cell therapy products. With regard to biosimilars, no specific scheme exists, but for glycoproteins, because of their structural complexity, a system making use of Greek letters identifies potential different glycoforms.

The objective of the meeting is to review current INN approaches for cell therapy and biosimilars. It has to be borne in mind that the INN experts have supranational responsibility; they do not represent individual countries or institutes but work towards a global WHO scheme. Also, there is a need to distinguish between nomenclature matters and regulatory

aspects as the latter are not part of the INN Committee's work, and there are no sanctions that the Committee can exert on how and to what extent INN get used.

INN policy needs to respond to changing needs, and in doing so new schemes must be driven by science and scientific developments. Would a one word name suffice for cell therapies, or will this require two as for gene therapy products? What might future developments be, which cell therapy products should be given INN, what guidance can be given to the INN committee? These are the topics for today's discussion.

Following this introduction to INN, **Dr Kevin Grant** (TGA, Australia) focussed on cell therapy products and the situation for regulating cell therapies in Australia. Cell therapy essentially started with blood transfusion in the 19th century, was fairly disastrous and only became reliable with the advent of blood typing. Bone marrow transplants appeared in the mid-20th century, and gradually over the past 20 years we have seen the rise of stem cells. Human cell therapies can be classed as two types, *autologous*, where 'self' cells are re-administered, e.g. as skin grafts, and *allogenic*, where donor cells are manipulated, expanded, and/or stored and used for treating a number of patients. It is doubtful that autologous cells can be named as the product cannot be registered; the product is a one-of and possibly the process could be registered but not the product. On the other hand allogeneic cells are more amenable to regulation and potentially INN could be assigned.

Stem cells, especially pluripotent stem cells, are currently the most likely type of cell therapy that could be registered. Several notable targets of interest are cancer (with a focus on stimulation of the immune system), neurological disorders, cardiovascular (to repair ischemic damage) and auto-immune disorders, e.g.,. lupus and diabetes. Cosmetic use of cell therapy has currently no scientific basis and care is needed to avoid inappropriate naming of such products. Gene therapy with direct administration of the vector into the patient has not boomed but the possibility of administration via cell therapy is attractive; such a product would be a cell therapy and not a gene therapy medicine.

In Australia the regulatory situation for cell therapies falls within the 'Biologicals Framework' of the Therapeutic Goods Administration (TGA). But the use of the term 'biologicals' needs to be qualified as standard biologicals (e.g. recombinant biotherapeutics, vaccines and blood derivatives) do not fall within this framework. Within the framework, cell therapies are assigned to one of four risk categories: Class 1 are those cells not manipulated in any way, e.g. some autologous cells; Class 2 for which there has been minimal manipulation such as storage or washing; Class 3 are those processed beyond 'minimal' but for which the process has not altered the phenotype of the cell; Class 4 are those cells whose biochemical, physiological or immunological properties have been altered. Classes 3 and 4 need to be registered with the TGA and listed as regulated substances and some kind of naming will be required. However, currently there is no naming policy although one is under discussion; at this point there are no Class 3 and 4 products registered.

Dr Guo Zhongping (Chinese Pharmacopoeia Commission - ChPC) provided an overview from China. In 2012 a special working group from the Chinese Ministry of Health and China's State Food and Drug Administration (SFDA) drafted strict requirements for clinical trials of stem cell products as these are medicinal products derived by new technologies. The scope of the document includes autologous and allogeneic stem cells, and derived progenitor cells or tissues from stem cells. It should be anticipated that the clinical effect will be superior to any existing method or that the disease to be treated has no effective intervention therapy, that the target disease is life-threatening or seriously impacts the quality of life, and that there is a great need for the medical treatment and for public health in general. Other key aspects covered include Good Manufacturing Practices (GMP) for the preparation and quality

control of the stem cells, pre-clinical studies for safety and efficacy, phase I, II and III clinical trials, quality standards and specifications, and a review from the ethics commission. Many other requirements and guidelines that impact on the preparation and use of stem cells have also been produced by the Chinese Ministry of Health and by the SFDA.

Currently in China, registration has been sought for twenty-seven different cell therapy products, including immune cells, tissue engineered cells and stem cells; stem cell products are generally for allogeneic use whilst the other categories of cells are mainly autologous.

R & D for cell therapy has been ongoing in China for some time and has developed rapidly into a variety of areas including cardiac, neurological, hepatic, bone and autoimmune diseases. Supervisory oversight and technical requirements are evolving and improving, and R&D takes place in a relatively comfortable environment with government support.

The ethics and safety issues of embryonic and pluripotent stem cells remain a challenge, as does the unequal progress of the different types of cell therapy. Currently few products have been approved for clinical assessment or licensed and there remains an urgent need for improved technical regulation and systematic surveillance to avoid misuse of immature technologies.

Nomenclature for cell therapies is beyond the existing policy for nomenclature of pharmaceutical substances which is regulated by the ChPC and provided in the Chinese Approved Drug Names; however new principles are under development.

The view of EU experts and in particular the Biologics Working Party (BWP) was provided by **Klara Tiitso** (EMA). The Advanced Therapies Regulation EC (No) 1394/2007 provides a definition of gene therapy, cell therapy and tissue engineered products as well as requirements for product approval and surveillance. The Regulation established the Committee for Advanced Therapies (CAT) and gives incentives in the form of scientific advice, certification and fee reductions with transitional periods also foreseen in the legislation. It should be noted that the EMA is not involved in approval of clinical trials, which is undertaken by individual member states.

To date no cell therapy product and only one tissue engineered product has been approved within the EU via the centralised procedure – ChondroCelect – with four further submissions under review. Approximately 40 requests have been received for clarification as to whether a particular product falls under the Advanced Therapies legislation and ~ 90 requests have been received for formal scientific advice.

Cell therapy products are provided with a common name and these are quite descriptive, for example the common name for ChondroCelect is “Characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins” whilst a tentatively agreed common name for a specific cell therapy product is “Allogeneic human aortic endothelial cells cultured in a porcine gelatin matrix” (the final decision on the name will be taken during the evaluation of the Marketing Authorisation Application) .

The EU experts appreciate the advantages of a global naming system with short names but find that with the field evolving fast and the complexity of the products that it is premature to develop a rigid INN naming scheme. Instead a standardisation of attributes to be captured in a common name would be favoured. Such attributes could include the origin of cells, their anatomical origin, differentiation status, cellular type, products class and manufacturing information.

A letter from the **Spanish Medicines Agency** was also tabled which supported the provision of INN for cell therapy products. Cell therapy is highly developed in Spain and due to a wide

disparity on names for the same product investigated in different clinical trials, the Agency has proposed a standardised formula for names to clinical trial sponsors. The aim was for a simple, flexible and transparent scheme that would guarantee the identification of cell therapies in trials and in clinical trial databases. The scheme comprises the assignment of seven attributes with a further two optional attributes. During consultation, two specific uses have been highlighted: first that the cellular type may not always be well defined and in such cases attempts should be made to define the cell type responsible for the mechanism of action, and second, it is recognised that certain attributes may be redundant for certain products, e.g. "liver hepatocytes".

Dr Ralf Sanzenbacher (Paul-Ehrlich-Institut, Germany) gave his views on the current situation regarding cell and tissue engineered products. Besides EU Regulation EC (No) 1394/2007, several EU Directives impinge on cell- and tissue-based products, e.g. Directives covering procurement of human cells, and on their processing, storage and distribution. Notably, related entities such as blood components and organs are covered by other provisions. In contrast to ATMPs regulated by EC (No) 1394/2007 in a centralized approach via EMA, most member states do not regard human tissue products as medicinal products. Some tissue preparations, e.g. muscle, heart valves, cornea, may contain vital cells but may still not be defined as medicinal products. Thus, in some cases the borderline can become difficult to define.

Somatic cell therapy products, autologous or allogeneic, are being used in a variety of conditions e.g. treatment of liver or autoimmune disease, wound closures, adoptive immmunotherapy, tumour vaccines, and the extent of processing can vary from minimal to complex involving e.g. activation, loading with peptides, differentiation and genetic manipulation; indeed the final products are often defined more by the process than the cell origin. Further factors to consider are that products can be very patient specific and that the active substance is often a cell mixture for which it is difficult define which cells are active and which might only be excipients or even impurities. Similarly, defining a matrix as part of the active substance or as an excipient is often challenging.

Most tissue engineered products focus on cartilage and skin repair whilst stem cell products are in development worldwide with a variety of modes of action and indications.

In considering an international nomenclature scheme, one has to bear in mind that this field is evolving rapidly and covers a very heterogeneous and complex range of products. Definitions and regulations vary between competent authorities and the active substance is often ill-defined or cannot be defined.

Dr Nana Kawasaki (NIHS, Japan) gave the Japanese perspective on nomenclature for cell therapies. Clinical studies on cell or tissue therapies in Japan fall under one of two categories – clinical trial or clinical research. Where the aim is for marketing authorisation, a product must undergo a clinical trial which is regulated by pharmaceutical law, the product must be manufactured under GMP and an IND review is performed by the PMDA. In contrast, where marketing authorisation is not sought and the objective is, for example, development of a new medical treatment, GMP compliance is not required and procedures are governed by the Medical Practitioners Act, ethical guidelines and institutional review boards. There are specific guidelines however for stem cell research and clinical research is reviewed by the MHLW. Clinical trials have been approved for a variety of cell and tissue based products whilst a large number of clinical research studies, some of which may proceed to clinical trial, are in progress.

With regard to a nomenclature system, for a cell therapy product, the JAN committee will designate a JAN whilst for medical devices the PMDA medical device team will consider a JMDN. Two medical devices have been approved in Japan – 'epidermal cell (autologous) for severe burns' and 'chondrocyte (autologous) for cartilage defects'. For both products a JMDN has been designated which translates roughly into 'human autologous graft tissue'. To date no cell therapy has been approved and no submission for a JAN has been made although the JAN committee has begun discussion on a naming policy. The JAN committee though would seek to harmonise with any INN policy for cell therapy products.

In the USA, in 2005, a naming scheme for cell therapies was developed by USAN and CBER (**Dr Kimberly Benton**, CBER, FDA, USA). Whilst most cell therapies are covered by the scheme, minimally manipulated hematopoietic cells, allogeneic cord blood, combination products and prophylactic vaccines are excluded. CBER/FDA has responsibility for regulatory oversight of cell therapies at both at the investigational stage and for marketing stage, through Investigational New Drug Applications or the Biologics Licence Applications (BLA) process, respectively.

In designing the scheme it was borne in mind that a name needed to be small enough to appear clearly on cryovials or other small product containers. According to the scheme, names consist of a prefix, two infixes (infix 1, infix 2), a stem and qualifier. The prefix is proposed by the applicant and reviewed by USAN, and provides uniqueness to the name. The first infix concerns manipulation of the cells such as selection/enrichment, fusion and transduction. Infix 2 focuses on cell type or source, and may be supplemented with a sub-infix for tumour cells to denote tumour tissue type. New infixes will be generated as needed. The suffix or stem for all cell therapies is *–cel*. Finally, the one word name is accompanied by a terminal qualifier denoting the autologous (*-T*), allogeneic (*-L*) or xenogeneic (*-X*) nature of the cell. Guidance is provided on the order of infixes, terms to be used for different types of manipulation and for infixes for different cell types. Finer details of manipulation such as activation with cytokines, are not included in the name and appear instead in the package insert.

To date 15 USAN names for cell therapy products have been provided. To cite one example, Provenge™ received FDA BLA approval in 2010. Its USAN is *sipuleucel-T*, whilst its chemical description is: specific active immunotherapeutic composed of antigen-loaded autologous antigen presenting cells designed to stimulate a T cell immune response specific for the tumor-associated antigen prostatic acid phosphatase (PAP). Provision also exists within this scheme for creating names for non-cellular immunotherapy products such as peptides or cell lysates. This provision was mentioned because it is included in the scheme, although it is not relevant to the focus of this meeting.

In discussion, two criticisms were levelled at the scheme's provision for naming non-cellular immunotherapy products, first that an alternative suffix to *–imut* r should be chosen, as *–imut* is reminiscent of 'mutation', and second that the *–imut* group will be overly heterogeneous. With respect to the cell therapy scheme's infix terms for manipulation, it was also suggested that a better definition of when to use *–fus* versus *–pul* would be valuable.

It was also noted that the USAN scheme will result in names with a minimum of 5 features/syllables whereas the EU and Spanish schemes suggests that maybe 6-7 or more features need to be captured, so this raises the issue of how the USAN system would cope with more features.

Dr Benton pointed out that combination products such as cells in a matrix would not be in the scheme due to their complexity and challenges with naming of matrix components that have been historically regulated as devices. However, in comparison with the proposal from Spain, product class and differentiation status are not covered in the USAN scheme. These differences would make it difficult to harmonise schemes. For stem cells, the USAN scheme focuses on cell or tissue from which the product originated rather than what the cells get differentiated into; however, one could potentially introduce a new qualifier regarding cell type.

Finally, it was noted that the USAN system gives rise to unique names whilst the Spanish/EU descriptive systems may not.

General Discussion

The participants were reminded that INN are widely used in practice by a variety of stakeholders and that INN Experts have to be communication specialists as limited information can be contained within a one (or maybe two) word name with a limited number of syllables; at the same time names that get created have to be unique, distinct and meaningful. Thus in creating a new scheme it has to be borne in mind that the amount of information that can be directly contained within the name will be limited.

There are parallels with the establishment of a scheme for monoclonal antibodies (mAbs) for which the INN consists of a stem (*–mab*), two substems (one for the origin/type of mAb and one for the target) and a unique prefix identifier. But with a minimum of four syllables and often rising to six or seven syllables, there have been linguistic difficulties. It is difficult to know what elements to include in an INN scheme for cell therapy products. The Spanish approach provides for up to seven attributes and for some cell therapy products there may be multiple indications. Also the mechanism of action may not be known at an early stage and at licensure an alternative mode of action may be established, whilst further detailed characterisation may result in a need to change the name of the cell. All this would be problematic, so designing a new scheme needs very careful consideration.

A further point to note, is that for drug/device combinations, the INN system focuses only on the active substance and no attempt is made to name the matrix in which the active substance is used. So, in any cell therapy scheme, names for scaffolds and matrices should be ignored and the focus should be on the active substance only, and from a regulatory viewpoint, a name should be short enough to enable it to appear on a cryovial; this could be a problem with overly long names. Source is a potentially important attribute for ethical reasons as some patients will not want the product if it derives from a foetus.

It was suggested that the INN Experts wait for a few applications first to learn what names sponsors might present to the Committee. To date, however, only one application has been submitted for a cell therapy INN (which was rejected) but there have been many enquiries about getting an INN for these products and the need for a naming scheme, so perhaps one should indeed proceed now in creating a scheme and not wait for applications. Caution again raises its head as one could start off designing a scheme, but if there is a need for adding further attributes as the science progresses, the system could become impossible.

Whilst the US FDA requires all cell therapies to be named, it was mooted that the INN Committee could assess situations on a case-by-case basis. For example, USAN names mixtures whilst the INN generally does not and so could INN name a subset only?

Autologous versus allogeneic

A major discussion point was what type of cell therapy product might get named and what not. There is a distinction between the types of human cells available for cell therapy; in *autologous* use, cells are taken from a patient, manipulated at the bedside or in a laboratory, possibly by a commercial organisation, and the cells are returned to the same patient only. This is very different from the *allogeneic* situation where cells are taken/donated, manipulated and banked, and made available to many patients.

Currently, development of autologous cells involves the development of a process and not a single product for widespread use, and however good that process might be, it was stated that it should not be given an INN. Indeed, if individual autologous products for use in a single person, developed using a common process, were included in an INN scheme, the programme could be overwhelmed with thousands of unique applications. In the event autologous cells get excluded, currently this would result in the exclusion of a majority of cell therapies. However, there was strong opinion that the INN committee should concentrate on those products that are likely to come into commercial use and will be approved by a regulatory authority, even if it is not clear at this time what will be commercially successful. It is for these products that there is justification for creating an INN scheme, even if it is for only a few products at this point in time. If in future the state of the autologous cell therapy requires a naming scheme it is probably not up to the WHO/INN to sort this out. In contrast to the above, the USAN scheme includes all types and an indicator of the cell type (autologous vs. allogeneic vs. xenogeneic) is provided within the name.

Conclusion

The INN programme has received many enquiries from developers of cell therapy products and there is a pressing need to consider the establishment of a naming scheme for them. Overall, there was no clear consensus on the adoption of an INN scheme for cell therapy products although in general it was felt that a scheme was eventually going to be required. Those not in favour of pushing ahead with a system were of the opinion that it was too early in the development of cell therapies, that too much remains unknown and that a naming scheme would be pre-mature. Cell therapy experts themselves, plus others, were more in favour of having an INN scheme and felt that the INN Committee should not wait, but consider now the possibilities within this evolving situation for an INN scheme.

In the event of creating a scheme, there was general agreement that the EU/Spanish approach is too descriptive and does not lend itself to a single name whilst the USAN system is over-weighted with syllables and uses terminal single letter qualifiers which are not allowed under INN rules. However, the USAN scheme is close to the INN system and could be used as a starting point. Many issues remain to be clarified and a broad view has to be maintained. A naming system will not appear in the short term, but plans have to be made to address this and, whatever the case, discussion needs to be continued at the next INN Consultation.

There was one point of agreement in that if autologous cells were to be named, that this would be naming a (commercial) process and not the product, and so the general feeling was that they should not be included in a naming scheme. Points that supported provision of INN for cell therapies were if the product were to be given to many people in a clinical trial, and if international commerce is expected. Clearly, further consideration needs to be given as to what could or should be included in a naming system and what not.

In conclusion, whilst the participants were far from unanimous on the creation of a scheme, it can be foreseen that there will be an INN requirement for cell therapy products. It may be premature to name cell therapies now, but if and when applications get submitted, the INN Experts should be prepared and need to consider the factors that would have to be taken into

account. For the next (56th) INN Consultation, a report should be prepared to describe a potential framework with which INN Experts could tentatively assess a cell therapy product.

Proposal for INN for biosimilars

A proposal for INN for biosimilars was made by Dr Kevin Grant of the Australian Therapeutic Goods Administration (TGA). The same proposal was also presented the following day to the plenary meeting of the 55th INN Consultation. For an account of this proposal and the subsequent discussion within the plenary meeting please see the Executive Summary of the 55th INN Consultation.