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**81st Consultation on International Nonproprietary Names for Pharmaceutical Substances**

**Geneva, 14-17 October 2025**

# *Executive Summary*

***International Nonproprietary Names (INN) Programme***

***Product Standards, Specifications and Nomenclature Unit (PSN)***
***Medicines and Health Products Policies and Standards Department (HPS)***
***Health Systems, Access and Data Division (HSD)***
***World Health Organization, Geneva***

**81st Consultation on International Nonproprietary Names for Pharmaceutical Substances**

**Geneva, 14-17 October 2025 (hybrid face-to-face/virtual meeting)**

## EXECUTIVE SUMMARY

### WELCOME and OPENING REMARKS

Participants were welcomed to the 81st INN Consultation by Mr Deus Mubangizi, Director of the Department of Medicines and Health Products Policies and Standards (HPS).

He focused his introduction on the re-structuring that has taken place within WHO, of the need to reduce personnel but at the same time maintain the important work of the organisation. HPS is one of six departments (down from thirteen) of the division of Health Systems Access and Data headed by the Assistant Director General Dr Yukiko Nakatani. Within HPS, Dr Raffaella Balocco, has been elevated to be Unit Head of not only the INN and Classification of Medical Products Unit (now team) but also two other teams, Norms and Standards for Pharmaceuticals (NSP), and Biologicals Norms and Standards and Transplantation (BNT). This brings together three WHO Expert Committees – INN, ECBS and ECSPP, plus the ATC/DDD advisory group – creating the largest normative unit for medicines within WHO. Overall, HPS hosts five of the six active WHO Expert Committees, and during the re-structuring, these had to be maintained under Article 2 of the WHO Constitution.

With healthcare products being the largest cost in a healthcare system, HPS remains highly important, but nonetheless had to be streamlined. During this process each division had to identify five core functions to be retained and the work of the INN impinges on all five HPS priorities but especially on its first priority of global norms and standards for quality, safety, and efficacy of medicines.

Mr Mubangizi went on to highlight that more than 280 requests including 240 new ones, are to be discussed in this Consultation. He remarked that INN remains totally important for international understanding and communication of drugs and that the INN continues to evolve, reflecting a growing need to maintain consistent naming principles. The new INN protein database is also important and is becoming an international reference model. Mr Mubangizi expressed his gratitude to fellow staff and to members of this committee who dedicate their own time to share their knowledge with WHO. He put on record that the work of this Committee is highly appreciated and he looked forward to the outcomes of the meeting.

Dr Balocco thanked the Director for his remarks and repeated her feeling of gratitude to her INN team and also to the Experts for their work in staying abreast of all the requests from her. She added that even with new limitations, WHO is an important organisation, and a privilege to work for.

### ELECTION of CHAIR, VICE-CHAIRS and RAPPORTEUR

Professor Sarel Malan was nominated to chair this Consultation, and this was agreed.

Professor Malan then requested the support of Dr Akinola Adisa and Mr Adrian Evans to be co-chairs of biologicals and chemicals respectively, and Dr Jim Roberston to be rapporteur, to which all agreed.

Professor Malan was privileged to be Chair and before commencing with the Consultation, requested a Tour de Table as there were several new members present.

### NOTES of the 80th INN CONSULTATION

The report of the 80th INN Consultation was tabled and adopted by all, and thanks were proffered to the rapporteur, Dr Robertson.

**NOMENCLATURE of INN**

During the 81st INN Consultation, 281 INN requests were discussed, including:

- 244 new INN requests, of which 136 were for biological substances
- 34 outstanding requests
- 3 objections

As a result of these discussions, 269 new names were selected, which are planned to be published in List 135 of proposed INN (p.INN) and COVID-19-related requests only in pending List 134. Three requests did not fulfil INN criteria (No INN), 4 were withdrawn by the applicant and 5 requests were deferred for future discussion.

Four new stems/substems were selected, two suffixes were promoted to the pre-stems list and it was decided to review the description of two stems before the 82nd INN Consultation.

**A BOOKLET for WELCOMING INN EXPERTS**

A booklet providing information to new INN Experts describing the goal of INN, the main tasks expected of Experts in naming drug substances and various documents that could be of value to new Experts has been drafted. It also highlights that the procedures for developing INN are posted on the School of INN website. It was suggested from the floor that a short list of definitions, for example of stems and substems, could be added as an annex.

**CONJUGATES**

With a view to harmonising the myriad complex names for conjugates, a subgroup of INN Experts met prior to this Consultation to discuss the issue, and the outcomes were reported. Four categories of conjugates were addressed: chelator/-reotide conjugates, derivatives of vedotin and tetraxetan, PSMA targeting substances, and oligonucleotide/peptide conjugates.

For chelator/-reotide conjugates, there was strong agreement that all chelator-peptide conjugates should be assigned 2-word names using the suffixes *-reotide* and *-xetan*.

For conjugates of tetraxetan, there have been inconsistencies in naming with the linker name sometimes part of the *-xetan* word and sometimes part of the conjugated moiety. Proposals to harmonise these ranged from the use of xxx-*xetan* with the infix *-tra-* if the radical is *tetraxetan* and an alternative infix for other chelators, to no prefix on *-xetan*, or even no indication of the *-xetan* moiety. For these conjugates, there was strong preference for use of xxx-*xetan* with an infix but excluding a *-tra-* infix.

For vedotin conjugates there was a similar strong preference going forward for the word to be *xxx-dotin* regardless of the linker and with exclusion of a *-ve-* infix in front of the *-dotin* suffix.

For naming conjugates of PSMA (prostate-specific membrane antigen) targeting agents, there was no clear consensus. There has been inconsistent use of the *-folastat* substem for inhibitors of PSMA versus the *-votide* substem for PSMA-binding peptides. Overall, there was a slight preference for conjugates to use *-folastat* or *-votide* depending on structure rather than the MOA.

For oligonucleotide-peptide conjugates, a 2-word naming scheme was approved at the 80th INN Consultation, with the first word having the *-rsen* stem (for antisense oligonucleotides) and the second peptidyl moiety a *-tide* name. Many experts were sympathetic to assigning a 1-word name given that the peptide moieties do not contribute to the MOA and serve only to transport the oligonucleotide across the cell member. However, not knowing to what extent a peptide moiety may or not be used on its own, and to avoid overly long complex 1-word names, a majority of Experts were in favour of retaining the 2-word scheme. Possibly, a 2-word name could be a default position, in which case a process should be specified under what circumstances a 1-word name could be assigned.

Two previous INN in which an oligonucleotide is linked to a sugar moiety to enable cell membrane transport, were assigned 1-word names.

The USAN is leaning towards a 1-word name for these conjugates but have still to vote formally on it.

## OPEN PROTEIN DATABASE (OPD)

An update on the OPD was provided showing on screen how Experts can easily access protein sequences prior to publication. The arrangement of protein structures can also now be visualised and data exported in text or picture format.

The OPD is also being adapted to provide a database of chemical structures specifically for use by INN Experts. Structures can be searched and compared, and is available on IDMIS. Such a development was well received by the Experts.

## CELL THERAPY WORKING GROUP

The cell therapy working group met on two occasions prior to this Consultation.

Names for chimeric antigen receptor (CAR) T-cell therapy substances are increasingly being requested and to date most have been assigned an INN with a common 19 letter component -*cabtagene autoleucel* plus a short fantasy prefix that confers uniqueness to the name. In an attempt to shorten them and remove at least one syllable, the group proposed to reduce the *-cabta-* infix to *-cab-*. This would allow more letters to be used in the fantasy prefix plus the *-ta-* component is technically redundant as the T lymphocyte aspect is contained in the second word. It was noted that USAN needs to be kept onboard with these changes and to maintain harmonisation.

The reduction of *-cabta-* to *-cab-* was approved by the INN Experts.

## LOOK-ALIKE INN and MIS-LABELLING

A case of INN mis-labelling on drug packaging in Australia was brought to the attention of the meeting. Eloctate® is a recombinant Factor VII (F8) containing the active substance *efmoroctocog alfa* packaged in five doses. However, the 1000, 2000 and 3000 IU packages showed the wrong INN, displaying *eftrenonacog alfa* which is a recombinant Factor IX, instead of *efmoroctocog alfa*. Both *efmoroctocog alfa* and *eftrenonacog alfa* are marketed by Sanofi, with the latter under the brand name Alprolox®. Also, the 3000 IU dose packaging of Eloctate® showed an incorrect potency of 2000 IU. The similarity of the INN and in the layout, colour and font of the packaging of both Factors appear to have contributed to this error. Ultimately INN with similar start and end need careful consideration when assigning INN. The error had been picked up by the end-user and was not present on the vials.

In discussion, it was highlighted that a wide variety of people are users of INN, many of whom are not healthcare personnel including distributors and wholesalers. INN beginning with the *ef-* prefix are an issue, although at the same time it is important to have it because of the difference in action of a drug with/without the Fc moiety. It was suggested that this could be discussed yet again at an INN Open Club meeting.

## ATC CLASSIFICATION SYSTEM

*Assigning ATC Codes*

Participants were reminded that whereas INN are assigned at an early stage of a drug's development, ATC codes are not usually assigned until a medicine reaches the market, although even then a code often does not get assigned. Furthermore, a drug substance is assigned a unique INN whereas it may have more than one ATC code depending on its therapeutic use and its route of administration. ATC classification is used in research, in administrative areas (such as procurement and cost) and in pharmacovigilance, and so it is important that marketed medicines get assigned an ATC code.

Use of ATC tends to be concentrated in North America and western Europe, probably due to the ATC coding system originating in Europe. Common drugs used in a variety of countries usually have an ATC code, but where there is a local manufacturer supplying local needs, the drugs typically do not have an ATC. Older drugs especially are more likely not to have an ATC and it would be good to address this. It would also be useful to identify newly marketed medicines systematically to ensure they get an ATC classification.

Certain codes also need to be improved, especially for fixed dose combinations (FDCs) some of which are not clearly identified or the classification is inappropriate. For example, there are several

FDCs containing chlorzoxazone (a muscle relaxant) along with an analgesic which need a clearer ATC assignment as some have non-informative codes. Clearer codes for FDCs of antimicrobial drugs are also needed.

*Global Antimicrobial Resistance and Use Surveillance System (GLASS)*

GLASS was launched by WHO in 2015 as antibiotic use varies significantly between countries, with patterns of both overuse and low access. More than 100 countries are now enrolled in GLASS and the surveillance methodology uses ATC classification and the DDD (Defined Daily Dose) per thousand inhabitants per day.

The 'AWaRe' (Access, Watch, Reserve) classification of antibiotics was conceptualised in 2017 to emphasise the importance of their use. The concept is that most infections can be treated by *Access* antibiotics as a first line of defence, then antibiotics with higher resistance potential are classed in the *Watch* group, while those in the *Reserve* group should only be used as a last resort for multidrug-resistant infections. The UN General Assembly has set a target that by 2030, 70% of global antibiotic use should come from *Access* antibiotics; however, data from 2022 show that only about one-third of 60 countries met this target.

Many antibiotic FDCs are classified by ATC and some contain both *Access* and *Reserve* antibiotics; however, it is difficult to monitor *Reserve* antibiotics present in such combination products. Also, the ATC has run out of codes for some combinations, and there are antibiotics with neither an INN nor an ATC code. The INN Experts would like to discuss these issues with the ATC Advisory Group.

*Discrepancy between INN and ATC Classification Systems*

The ATC was notified by the Spanish Medicines Agency that in Spain, medicines that contain metamizole may include it either as the sodium salt or the magnesium salt. An ATC code (N02BB02) exists for metamizole sodium, but there is no corresponding code for metamizole magnesium. Consequently, the Agency has requested the ATC to either redefine N02BB02 to apply simply to metamizole or retain N02BB02 for metamizole sodium and add a new ATC code for metamizole magnesium.

To decide if there should be two separate ATC codes, it may be useful to assess if there are differences in the pharmacokinetics or pharmacodynamics between the two salts. A further aspect to consider is the level of sodium being administered if a patient is also on other sodium salt medication because of the increased cardiovascular risk. Ultimately it is for the ATC Advisory Group to decide, but given that the recommended single and maximum daily doses are similar for both salts, the ATC code N02BB02 could be redefined simply for metamizole.

In discussion, it was highlighted that there is also a discrepancy in the INN; metamizole is not an INN, the INN is *metamizole sodium*, which technically should be a modified INN (INNM). This could be solved by assigning an INN to metamizole, and the two salts would be modified INN (INNM). The Secretariat noted that this is an old INN but agreed that metamizole could be assigned an INN. Metamizole is banned in many countries but its use continues in some.

*INN and ATC classification of anti-psychotic drugs*

The INN Secretariat was contacted by Professor Joseph Zohar, an eminent psychiatrist, to discuss nomenclature of anti-psychotics. He was aware of the weakness of ATC classification of anti-psychotics but happy to see that for INN more weight was being put on the MOA rather than the chemical structure. However, the MOA of psychotics generally remains unknown; such drugs act on many receptors and it is a complicated area. It was suggested that a working group on anti-psychotics is formed, and to include an ATC group member.

**SCHOOL OF INN (SoINN)**

The 24th SoINN Steering Committee meeting took place the day before this Consultation. The first and most important part of the meeting was devoted to activity reports from pilot centres which have three main missions regarding INN: promotion, teaching and research, for which there has been increasing activity. The number of pilot sites has increased to nine.

Presenting the INN system to students and using INN whenever medication is discussed in a course, has become almost systematic in the universities where pilot sites are located. This applies not only to pharmacy students, but in some sites also to dentistry, nursing, and nutrition students. At the Faculty of Pharmacy in Monastir University (Tunisia), every teacher must sign a commitment to systematically use INN. The promotion of INN also involves speaking at conferences, symposia, and meetings of learned societies. Two pilot sites, in Cape Town (South Africa) and Novara (Spain) reward students who complete SoINN online courses with points and credits.

Since the beginning of SoINN, it has been asserted that INN and their stems, as well as the ATC classification, can be useful for improved teaching of pharmacology. Two initiatives demonstrate this. The Barcelona (Spain) site has developed a pharmacology course on antibiotics using stems, the ATC classification, and 'Stems in Pills'. The Alcala (Spain) site, following the Grenoble (France) site, has produced card games, particularly for teaching pharmacokinetics. These pedagogical innovations have not only been put into practice, but have also been evaluated by students and will lead to publications. At the next INN Consultation, Experts will be asked to judge posters of students from Grenoble and Syria on the topic 'travelling with INN'.

Various research projects lead to master's degrees and theses are underway in Barcelona, Sao Paulo (Brazil), and Monastir. In Grenoble, a master's thesis was completed in the University's Linguistics Department on the theme 'Use and Misuses of INN through Corpus Analysis'. All such work is intended for publication.

In the second part of the meeting, reserved for Steering Committee members, important decisions were made including creation of an information page on pilot sites' activities on the WHO and SoINN websites, and organisation of a face-to-face meeting of the pilot sites during the first half of next year. Also, there are now 30 chapters of 'Stems in Pills' on the SoINN website, and the e-book of these is currently being published. The online course on the chemical aspects of INN is to be updated. Finally, the SoINN is maintaining contact with the WHO Academy, including an exchange of links on the websites.

Any interested colleagues are welcome to join the SoINN and/or submit ideas for future action.

The work of the SoINN committee was acknowledged by Dr Balocco, INN Team Lead/PSN Unit Head.

## COLLABORATORS' UPDATES

The following are reports presented at the 81st INN Consultation by intergovernmental organizations, specialized agencies and related organizations, both national and international.

### Brazilian Pharmaceutical Substances Nomenclature Committee (CTT DCB)

On 12 June 2025 representatives of the School of INN (SoINN) in Brazil and Professor Albert Figueras, INN Programme consultant, attended the ordinary meeting of the CTT DCB[1], along with the president of the Brazilian Pharmacopoeia, Dr Tais Rocha. The SoINN initiative was presented and possibilities of collaboration between the SoINN and the Brazilian Pharmacopoeia were discussed.

On 23 June the Brazilian representatives of the SoINN and Professor Figueras presented the activities of the School in Brazil at a virtual meeting with the Educational Program of the Brazilian Academy of Pharmaceutical Sciences (ACFB). A recording of the session is available online[2].

Dr Raffaella Balocco, Team Lead INN/Unit Head PSN was invited to participate in the celebration of the 100th anniversary of the Brazilian Pharmacopoeia, which will take place in June 2026.

### EDQM

The European Pharmacopoeia (Ph.Eur.) is now online-only and has been completely reformatted; the printed version is no longer produced. There are still three issues published per year, but are now grouped into a single edition consisting of issues 12.1, 12.2, 12.3 for 2025.

A new platform has been launched for the European Drug Shortages Formulary. The formulary will provide monographs that describe methods for the preparation and quality control of unlicensed pharmaceutical preparations that may be needed when licensed alternatives are unavailable. The formulary contains a first draft monograph for amoxicillin capsules, as well as two general texts describing the purpose and principles of the formulary.

This is in addition to the European Paediatric Formulary, which gathers together the most appropriate extemporaneous formulations currently described in national formularies or in other existing well-established monographs in Europe. It can provide clinicians and pharmacists with appropriate formulations for use when no licensed product is available for paediatric use.

New guidelines have been published relating to the classification of active substances as regards their supply (prescription and non-prescription status). They are intended to help national competent authorities, marketing authorisation holders and other interested parties establish whether a medicinal product should be available with or without a prescription, a decision that depends on several factors: the characteristics of the active substance and pharmaceutical form, the therapeutic indications and the safety profile, as well as the extent to which healthcare professionals' expertise is needed to diagnose and treat the condition for which the medicinal product is to be used. The nature and degree of any potential risk of misuse or incorrect use are also considered.

Finally, it has been noticed that ChemDraw has changed the way that dashed bonds are interpreted, so they are used as coordination bonds and not stereochemical bonds. This causes significant problems for drawing structures for INN and for pharmacopoeias that follow the INN style, including the Ph.Eur. Currently, an older version of ChemDraw has to be used but this will not be sustainable indefinitely. If Revvity Ltd fail to produce a patch or an alternative workaround, alternative software choices may need to be considered.

### European Medicines Agency (EMA)

The Quality Innovation Group (QIG) is an operational expert group that has been set up to support the development and registration of innovative technologies and products. The Group's work helps to avoid regulatory barriers and adapt regulatory guidance while ensuring products meet the required quality, safety and efficacy standards. It aims to provide coherent advice to drug developers during

[1] Thematic Technical Committee of Brazilian Common Denominations for Pharmaceutical Substances /Brazilian Pharmacopeia

[2] https://www.youtube.com/watch?v=gAqNDQjoik4

the product development lifecycle. This can be done during regulatory procedures, such as scientific advice or protocol assistance, initial marketing authorisation applications or post-authorisation procedures, and during informal information-sharing meetings with individual developers, which can help identify potential regulatory issues in development programmes.

The QIG's main working areas during 2023-24 were platform technologies, process models, digitalisation and automation of manufacturing and control, and decentralised manufacturing and continuous manufacturing (of biologicals and end-to-end continuous manufacturing). The group's main focus for 2025 is personalised medicines.

The QIG holds listen-and-learn focus group (LLFG) meetings with stakeholders from industry, academia and international regulators to hear about regulatory challenges developers face in relation to innovative products, processes, control strategies and facilities, and to identify potential solutions together. More information on QIG activities and meeting reports are available on the dedicated EMA webpage[3].

The most recent LLFG meeting covered the topic of manufacturing of personalised medicines. At the meeting some case studies proposed by stakeholders (e.g. ATMPs, antisense oligonucleotides, 3D printing) and a focus on scientific challenges and solutions that can support development of these medicines in the future were discussed[4].

EMA noted the INN discussion on a faecal microbiota substance and informed the INN that the Agency has received a Marketing Authorisation Application (MAA) for Xervyteg (Allogeneic faecal microbiota, pooled) under an orphan designation[5] [6]. The product is indicated for treatment of adult patients with acute-graft-versus-host disease and the MAA is currently under evaluation.

**Pharmaceuticals and Medical Devices Agency (PMDA), Japan**

Since the 80th Consultation, the Japanese Accepted Name (JAN) Expert committee met on two occasions and 45 names were published. With regard the Japanese Pharmacopoeia, Supplement 2 to the 18th edition was implemented in June 2024. The English version can now be freely downloaded on the Japanese government's website. The 19th edition is now under preparation.

The Pharmacopoeial Discussion Group (PDG) welcomed the Korean Pharmacopoeia as a candidate participant. The Group now includes the Korean Pharmacopoeia, along with the European Pharmacopoeia, the Indian Pharmacopoeia Commission, the Japanese Pharmacopoeia and the United States Pharmacopeia. The WHO continues as an observer. The PDG held its annual face-to-face meeting on 30 September to 1 October in Tokyo. The meeting was very successful.

**Therapeutic Goods Administration (TGA), Australia**

In September 2025, the Therapeutic Goods Administration (TGA) issued a safety alert advising consumers to avoid imported, unregistered GLP-1 weight-loss products - often marketed as 'GLP-1 peptide' oral drops - due to significant risks, including being fake, containing undisclosed harmful ingredients, and being sold through scam websites with false claims of regulatory approval. This complements ongoing enforcement actions to stop unlawful supply of prescription-only weight-loss medicines in contravention of the *Therapeutic Goods Act 1989* (the Act).

Medicines entered in the Australian Register of Therapeutic Goods (ARTG) for supply in Australia must comply with the requirements for labels set out in the Therapeutic Goods Order No. 91 -

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[3] Quality Innovation Group | European Medicines Agency (EMA)

[4] meeting-report-quality-innovation-group-qig-listen-learn-focus-group-llfg-personalised-medicines_en.pdfFourth listen-and-learn focus group meeting of the Quality Innovation Group

[5] June 2, 2025: MaaT Pharma Advances Toward Commercialization And Submits Marketing Authorization Application to the European Medicines Agency (EMA) for Xervyteg® (MaaT013) in Acute Graft-versus-Host Disease - MaaT Pharma

[6] EU/3/18/2083 - orphan designation for treatment of graft-versus-host disease | European Medicines Agency (EMA)

Standard for labels of prescription and related medicines (TGO 91) and in the Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92). TGO 91 and TGO 92 were implemented in 2016 and will sunset in 2026. Efforts are underway to commence public consultations soon and meeting participants were requested to be on the lookout for the consultation to comment or learn more about these labelling Orders.

TGA is also seeking feedback on the current usage of paper information included in the packaging of self-administered injectable medicines. This consultation aims to understand whether the paper copy of the Product Information (PI) document is helpful for patients and carers.

Public consultations currently ongoing can be found on the TGA website https://www.tga.gov.au/

**United States Adopted Names (USAN)**

The 2025 summer USAN Council meeting took place on 12-13 June in Washington D.C., hosted by the United States Pharmacopeia (USP). Names for 33 drug substances were reviewed and discussed. Nine new stems and infixes were approved and added to USAN's stem list, while 6 new stem definitions were discussed and approved. Meeting topics discussed also included: a negotiations update, USAN website metrics, the March 2025 INN Consultation results, ISMP and the FDA's medical error reports, a USP update, a Mab update and a CBER Presentation on Nomenclature for Gene and Cellular Therapy Combination Substances.

Twenty-one INN applications for proposed USAN were prepared and forwarded to the INN Programme to be discussed at the 81st INN Consultation.

The USAN on-line application portal went live on 8 September 2025 and will allow all USAN applications to be filed online.

From January through September 2025, USAN staff have processed, researched, and made recommendations for approximately 230 USAN applications and forwarded this information to the USAN Council for their review and name selection. Also, through September 2025, 220 USANs have been adopted for 2025 while revenue from 8 other applications was also realized. Currently, there are approximately 143 active USAN negotiations.

The 2025 Winter meeting of the USAN Council is scheduled for 5 December 2025 and will be a virtual meeting.

**United States Pharmacopoeia (USP)**

USP is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines. It is working to strengthen the global supply chain so that the medicines people rely on for health are available when needed and work as expected.

Generic medicines are essential to improving patient access to important drug therapies. They account for approximately 90% of prescriptions filled in the United States, contribute to lower prescription drug costs and help save trillions of dollars. For some patients, the availability of generics may determine whether they can access and afford treatment.

Complex generics are a growing category of products that are characterized by complex active ingredients, formulations or routes of delivery. Examples include inhalers, injectables, ophthalmic solutions and suspensions, and transdermal patches. Patients rely on complex generic drug products for many indications, including chronic conditions such as diabetes and asthma. Due to their complexity, generic versions of these drug products can be difficult to develop, so they are less likely to be available than other generics. These products also may be significantly more prone to drug shortages from supply, demand and regulatory issues. For patients, that can mean less access to medicines they need. USP is working with stakeholders across the medicines supply chain to understand the scientific and regulatory issues associated with complex generics to reduce barriers to their development and assessment, making them more accessible to the patients who need them.

The Global Substance Registration System (GSRS): the USP team in collaboration with FDA provides a standardized framework for identifying, registering, and sharing information about substances used in medical products including chemical, biological, proteins and polymers. Each

substance is assigned a globally unique identifier (UUID), ensuring consistency across databases and regulatory submissions.

**World Customs Organisation (WCO)**

The WCO undertakes tariff classification of INN pharmaceutical substances in the Harmonized System Nomenclature. The Harmonized System Committee, at its recent 76th Session, re-examined cyclosporin (INN) and reclassified it according to structure, as it did not meet the Harmonized System Nomenclature criteria for immunological products of heading 30.02.

Meanwhile, intersessional work on the new INN proposed lists 132 and 133 has already started and the two lists will be examined at the forthcoming Scientific Sub-Committee Session in January 2026. There will also be a review of the classification of all INN with the stems *-kinra* and *-fermin* to ensure that all of them have been classified in a consistent manner, alongside the pending classification of *efdoralprin alfa* (pINN 131) and *efsudenermin alfa* (pINN 131).

The WCO looks forward to discussing the classification of new INN substances that the WHO will submit to the future sessions of its Scientific Sub-Committee. The WCO representative also expressed the appreciation of the WCO Secretariat for the ongoing and valuable technical advice provided by Dr Lasseur of the INN Secretariat to the Scientific Sub-Committee with respect to the INN classification examinations.

**World Intellectual Property Organisation (WIPO)**

WIPO informed its Member States of the publication by WHO of List No. 133 of Proposed INN and List No. 93 of Recommended INN, and confirmed their successful integration into the WIPO Global Brand Database.

In addition, it was reported that WIPO organized a Training Workshop for the Developing Countries Vaccine Manufacturers Network (DCVMN). The workshop included multiple sessions on Intellectual Property and Vaccines, covering a wide range of topics such as Innovation in Vaccines and Applicable Intellectual Property Strategies that included patents, trade secrets, brands, packaging, and design.

The session on brands also addressed International Nonproprietary Names (INN) as part of the discussion, emphasizing the importance of brand strategy in ensuring effective product differentiation within the vaccine market when developing logos and brand names for vaccines.

**CLOSE of MEETING**

The Chair was thanked for leading the experts through the meeting; it had been a long week and the work continues to grow.

The Chair in turn expressed his gratitude for the support he gets from the INN Secretariat that allowed the Experts to move quickly through the meeting without sacrificing quality.

**Next meeting**

The 82nd INN Consultation will be held in Geneva on 20-24 April.

**OPEN SESSION for INN STAKEHOLDERS**

**81st Consultation on International Nonproprietary Names (INN) for Pharmaceutical Substances**

**WHO HQ, Geneva, 14 October 2025**

The Stakeholders Session held in conjunction with the 81st INN Consultation was opened by Dr Balocco, Team Lead INN Programme and Classification of Medical Products/Unit Head PSN, who welcomed all to the meeting. She reminded participants that these sessions are open to stakeholders only and not for external dissemination as some presentations may be confidential and not to be shared outside.

The meeting was chaired by Professor Sarel Malan, who looked forward to the presentations and assured presenters that the INN Experts will listen and give due consideration to their requests during the 81st INN Consultation.

**PYC Therapeutics**

PYC Therapeutics made representation to argue for a one-word name for two peptide-phosphorodiamidate morpholino oligomer (PPMO) substances that had previously been assigned two-word names, using the *-rsen* stem for the oligomer and the *-tide* stem for the peptide moiety. The company emphasised that the oligonucleotide moieties of the conjugates confer the mechanism of action (MOA) of the drugs whilst the peptide component is a tissue uptake enhancer that does not affect the MOA. A precedent for a one-word name for a PPMO, that of *vesleteplirsen*, was highlighted, whilst GalNac-oligonucleotide conjugates also receive single word INN with the name focusing on the oligonucleotide and no separate word for the GAlNac moiety which simply enhances tissue uptake. Furthermore, the PMO moiety is unlikely ever to be marketed by itself as it would not be active and the peptide component does not warrant a separate word in the name as it is simply a tissue uptake enhancer. With names for peptides using the stem *-tide* already at very high levels, the company could not see the logic in providing a two-word name for their PPMO substances. In response to questions, the company informed the Experts that the conjugate is stable and the peptide does not dissociate after administration. Also, that if the two components were administered as a mixture and not a conjugate, there would be no effect as the oligomer on its own would not be taken up by the cell.

**Mikrobiomik Healthcare Company, S.L.**

Mikrobiomik has developed a novel first-in-class Full Spectrum Purified Intestinal Microbiota medicine which has shown non-inferiority to *fidaxomicin* in clinical trials of treatment of *C. difficile* infection. Donors of faecal samples are carefully screened and the validated donor faeces are subjected to a GMP certified manufacturing process involving homogenisation, centrifugation, lyophilisation, and encapsulation. Its mode of action involves bacterial competition, immune system modulation and microbiome balance, and is presented lyophilised in acid resistant capsules. A previous request for an INN had been rejected and the company were present to describe in detail progress made in the clinic and the manufacturing process in order to convince the INN Committee of the need and value of an INN for their product, noting that it has an active ingredient, a name, a specific formulation and specific properties.

In discussion, the company acknowledged that whilst it aims to maintain a constant number of organisms per treatment, the level and diversity of the species vary from donor to donor but not significantly. Also, no specific mechanism of action has been identified.

**ExeGi Pharma, LLC**

ExeGi Pharma is developing a live biotherapeutic product (LBP) comprising an 8-strain blend of lactic acid bacteria to reduce high bowel movement frequency in patients with an ileal pouch-anal anastomosis. A previous INN request had been turned down and the company requested reconsideration of this decision emphasising that the substance has a clearly defined composition that

distinguishes it from other LBPs, with each strain present in a specific ratio. Each strain has its own distinct biochemical property and the specific combination of the eight strains works by decreasing metalloproteinase enzyme activity, thereby increasing levels of IL-10 and reducing levels of proinflammatory cytokines, such as IL-1α, TNF-α, and IFN-γ.

The company highlighted that there are >100 clinical trials of LBPs ongoing with even more in preclinical development and there will be a need for a regulated INN system for tracking and prescribing and to avoid confusion between similar-sounding commercial products. The company also highlighted that several INN for bacteria already exist, albeit for those that have been genetically engineered, and the *-bac* stem used for these could apply to their LBP, using the suffix *-lactibac*. The company saw parallels with the development of cell therapies, complex substances for which INN were not initially assigned but now almost 200 cell therapy INN exist.

In discussion, the company agreed that any change to the mixture would necessitate a new INN as it would be a new product; plus, regulators would not allow removal or addition of a strain.

**Alliance for Safe Biologic Medicines (ASBM)**

Biologics medicines are expensive and with continued pressure on healthcare budgets, there has been a tremendous increase in the use of biosimilars in the USA and the EU. There is also pressure to speed up marketing authorisation with a draft paper by the EMA proposing a streamlined pathway for biosimilars that makes more use of robust analytics and less of comparative efficacy studies when analytical comparability is strong. The US FDA has likewise moved to de-emphasize certain clinical switching data for some designations, again reflecting confidence in modern analytical tools. As a result, post-authorisation surveillance and pharmacovigilance has become much more critical for biosimilar medicines, yet many highly similar but different biologics products continue to share a non-proprietary name. The FDA's distinct suffix-bearing non-proprietary names for biologics supports accurate attribution, and the benefits of a WHO-led global standard of distinct nomenclature would benefit the least economically developed countries of the world, which lack resources to build advanced national or regional pharmacovigilance systems. Distinct naming is also critical for attribution of safety and effectiveness to the exact medicine used. In this respect ASBM continues to support the INN Group's recommendations for its Biological Qualifier (BQ). There is strong benefit to a global distinct nomenclature standard given the proliferation of biosimilars and the continued global push for significantly reduced clinical data.

In discussion, the impact of factors beyond a biosimilar itself were discussed, such as differences in closures and packaging, and in drug administration devices, that can impact the effectiveness and safety of the molecule.

**Close of session**

The Chair thanked all presenters and closed the meeting.