**INTRODUCTION**

The THREE LETTER CODE (TLC) was introduced as a dosage Form Code in the audits during the middle of the 1960s.

~~A large number of new dosage forms have appeared since that time and it was considered that revision of the system was required in order that a unified, worldwide classification could be developed.~~ The Annual General Meeting of the EPHMRA in 1984 decided to create a Working Party to discuss suggested improvements to the classification, and members were appointed from representative countries and IQVIA. ~~This group based their work upon proposals, which were already under consideration between some members and IQVIA.~~

The result of the Working Party deliberations was the NEW FORM CODE (NFC) which was accepted for ~~the~~ worldwide introduction at the 1985 AGM of EPHMRA. At that meeting it was also agreed that the New Form Code Committee should assume responsibility for further improvements and development of the NFC in addition to the allocation of correct codes.

In 1988 the NFC replaced the TLC ~~in the audits and on the databases. As far as possible the conversion had been completed automatically using IQVIA programs based on the "form descriptions". Where that description was incorrect, assistance was given by the NFC Committee.~~

**All users are requested to inform either IQVIA or members of the NFC Committee if they discover an error or believe that a code allocation may be in doubt**.

Since the main objective of the NFC is to maintain an international uniformity of the coding structure for the audits and the databases, it is important that the classification remains simple and easy to understand. Only if this is achieved for all forms and countries will it be possible to use the code for international investigation of dosage forms.

These notes are known as the New Form Code Classification Guidelines, and are intended to be used in conjunction with the Classification. This **English** version of the Guidelines is the authorised, definitive version produced by EPHMRA.

Within these Guidelines the terms "active ingredient" and "active substance" are synonymous and used interchangeably. These terms cover chemical, biological, biotechnical, living (e.g. fly larvae) and synthetic agents and extracts be they tissue plant or natural.

**A.. Oral Solid Ordinary**

All oral solid ordinary forms with a systemic effect.

Some products with a local effect in a scientific sense are included here, e.g. antacids with a local effect on the mucous membranes. This group also contains some oral solid forms where the systemic effect is either doubtful or not evident.

Generally speaking, all oral solid forms are included with the exception of those for disinfection or anaesthesia in the oral cavity or larynx which are in K…

Effervescent and soluble tablets for systemic use are included in this group. Also included are powders or granules to be sprinkled onto food.

Semi-solid foods e.g. puréed fruit or vegetable and yogurt, are included here.

**B.. Oral Solid Long-Acting**

All oral solid forms described under A.. provided they are declared to be long-acting or similar, as specified under the Classification Rule 2.

**D.. Oral Liquid Ordinary**

All oral liquid ordinary forms with a systemic effect.

Some products with a local effect in a scientific sense are included here, e.g. antacids with a local effect on the mucous membranes. This class also includes foods and certain forms to which liquid has to be added before use.

Effervescent and soluble tablets are excluded from this group; they are included in group A.

**E.. Oral Liquid Long-Acting**

All oral liquid forms described under D.. provided they are declared to be long-acting or similar, as specified under Classification Rule 2.

**F.. Parenteral Ordinary**

All parenteral ordinary forms with a systemic effect.

Forms with a topical effect only are excluded and allocated into one of the topical first letter groups. This applies mainly to irrigation, perfusion and dialysis fluids which have the first letter M..

Parenteral forms of local anaesthetics, muscle relaxants or sclerosants which are injected are included in this group. Also included are anticoagulant and preservative solutions to be mixed with blood, for blood transfusions and plasmapheresis. However, catheter lock solutions are classified in V.. as these are intended to ensure the patency of the catheter, not for human use.

**G.. Parenteral Long-Acting**

All parenteral forms described under F.. provided they are declared to be long-acting or similar, as specified under the Classification Rule 2.

**H.. Rectal Systemic**

All rectal forms with a systemic effect.

Excluded are rectal forms used for evacuations and haemorrhoids where the effect is topical. These are classified under the first letter M..

**I.. Nasal Systemic**

Forms for nasal application with systemic effect are included here.

**J.. Other Systemic**

This group contains all other forms with a systemic effect which are not mentioned in the previous groups. Included here are transdermal therapeutic systems such as nitrate patches, which have a systemic effect but are administered topically.

Inhalation narcotics are included as are other inhalers with a systemic effect, for example, inhalers containing ergotamine. However, inhalation aerosols, liquids and powders for asthma are classified under R..

**K.. Oral Topical**

All forms for a local effect on the mouth, teeth and throat including those for disinfection and analgesia. Injectable forms for local anaesthesia are excluded; they are classified with the first letter F.. Forms used primarily on the lips, e.g. anti-viral lip products, are in M..

**T.. Vaginal/Intra-uterine**

All vaginal applications. Products for vulval application only are also included here.

Ovuli, globuli, pessaries, intra-uterine devices, vaginal suppositories etc are included here.

Also included are ointments, creams and liquids for vaginal application.

**V.. Non-Human Use and Others**

The defining characteristic is that forms classified in this group have no direct therapeutic or pharmacological effect on the human body; contact is not excluded. Therefore, laboratory tests, urinary sticks for diagnostic tests, catheter lock solutions, aerosols for disinfection of rooms, fumigating candles, inhalation devices, empty syringes/injection pens and so on, are included here.

Other forms which cannot be classified in the groups mentioned above and bulk products used as raw materials are included here.

**Z.. Unknown**

This group is only for forms with unknown applications.

Forms classified here should be corrected as soon as the exact information becomes available. Z.. is a code for 'temporary' use only.

**.D. SOLID SPECIAL FORMS**

~~Capsules consist of active substance(s) enclosed in a shell. The active substance may be in a number of forms e.g. powders, granules, pellets or as a liquid. Each capsule is a unique unit of use i.e. a dose consists of one or more capsules, as prescribed.~~

**.DD PELLETS**

Include coated and uncoated pellets, microtablets, micropellets and microcapsules. Unit dose forms of these are also included e.g. sachets.

Pellets supplied as unit dose sachets used to prepare oral liquids are classified in DEP. All other unit dose pellets are classified in .DD.

**.DE LOZENGES**

Forms described as lozenges or pastilles which are oral solid dosage forms placed in the mouth where they slowly dissolve and liberate the active ingredient. They can contain antiseptics, antibiotics, local anaesthetics etc for a topical effect and also substances for a systemic effect e.g. vitamins.

Forms which are specially formulated as lozenges or pastilles but can also be swallowed are also in .DE.

**.DF CHEWING GUM**

Chewing gum.

**.DG SWEETS/CANDY/BONBONS**

Sweets, candy and bonbons.

**.DN OCULAR THERAPEUTIC SYSTEMS**

Ocular therapeutic systems are inserted into the upper or lower conjunctival sac or are surgically implanted in the eye. They are designed to provide a continuous release of the drug, for example, Ocusert (May & Baker), NODS (Smith and Nephew), Retisert (Bausch&Lomb). Also included are contact lenses containing active substance e.g. ACUVUE® Theravision® with Ketotifen.

**.DP CUBES**

Cubes, solid pastes divided in the form of cubes.

**.EM. UNIT DOSE POWDER INHALER NON-REFILLABLE**

Non-refillable unit dose dry powder inhalers activated by inspiration of breath (breath-actuated) e.g. Accuhaler/Diskus (GlaxoSmithKline). These deliver a unit dose of dry powder from a blister containing a pre-measured single dose of powder.

**.EN UNIT DOSE POWDER INHALER REFILLABLE**

Unit dose powders e.g. Becodisks, Ventodisks for use with refillable breath-actuated devices e.g. Diskhaler. These deliver a unit dose of dry powder from a blister containing a pre-measured single dose of powder. The Diskhaler device without the powders will be in VZY.

**.EP UNIT DOSE POWDERS**

Powders and granules (coated or uncoated) in unit dose packs. This includes gargles, mouthwashes and oral systemic suspensions supplied as powders or granules in sachets. Sachets are paper-covered unit dose packs. The paper is often coated with aluminium or a plastic film to protect the ingredients from humidity.

Unit dose powder inhalations are in .EM or .EN. Breath-actuated, metered-dose powder inhalers e.g. Turbohaler (Astra) or Clickhaler (Celltech Pharm, UK), are classified here. These products release a metered-dose from a reservoir of powder.

Pulmonary surfactants supplied as dry powder for reconstitution before use are classified in REP e.g. Exosurf (GlaxoSmithkline, USA).

Note that effervescent or soluble powders and granules in unit dose form are classified here and not in .EH and .EK.

Pellets supplied as unit dose sachets used to prepare oral liquids are classified in DEP. All other unit dose pellets are classified in .DD.

**.EX ENEMA POWDERS**

Powders to prepare enemas.

**.EY OTHER POWDERS/GRANULES**

Other special forms of powder or granules e.g. enteric coated granules.

**.NF INTRADERMAL PRE-FILLED SYRINGES**

Pre-filled syringes and cartridges with needle units indicated for intradermal use only.

**.NH PRE-FILLED AUTOINJECTORS**

Disposable, pre-filled automatic injection devices (autoinjectors), independent of the route of administration are included here e.g. SureClick. Autoinjectors are easy to use and are intended for self-administration by patients. With an autoinjector, the dose is automatically given by the device once triggered using an activation button, pressure or similar.

Autoinjectors classified here contain active ingredient in a pre-filled syringe or cartridge pre-enclosed within the injection device. Empty autoinjectors are classified in .ZY.

Also included here are disposable wearable injectors that deliver an injection over a longer period of time e.g. Pushtronex system.

Pre-filled manual self-injectors are classified in .NJ.

**.NJ PRE-FILLED MANUAL SELF-INJECTORS**

Disposable, pre-filled manual self-injection devices, independent of the route of administration are included here e.g. SelfDose. Manual self-injectors are easy to use and are intended for self-administration by patients. With a manual self-injector, the dose is given by the patient using continuous manual pressure on the device to both drive the needle into the skin and also to deliver the dose.

Manual self-injectors classified here are single dose and contain active ingredient in a pre-filled syringe or cartridge pre-enclosed within the injection device.

Pre-filled autoinjectors are classified in .NH while pre-filled injection pens are classified in .RF and .RG.

**.NS INSTILLATION PRE-FILLED SYRINGES**

Pre-filled syringes for instillation.

**.NY OTHER PRE-FILLED SYRINGES**

Other special pre-filled syringes. Pre-filled syringes for intra-articular, intrathecal and epidural use only are included here. Pre-filled syringes for intra-arterial administration are classified .NA.

**.Q. INFUSIONS**

Includes products intended only for administration by infusion. Products that may be both infused and injected are classified in the relevant ampoule, vial, pre-filled syringe or cartridge/pen class.

Infusion is defined as a slow injection, given over an extended time. Products described as for administration by slow injection are included here. These may specify the administration duration e.g. inject over 7 minutes, and are often recommended to be given using an administration kit, but may also be given by manual push method.

Infusions are not differentiated based on route of administration (beyond exceptional infusion types such as intracerebroventricular). Subcutaneous infusions are classified alongside IV infusions etc.

Dialysis, irrigation and perfusion solutions are also included here.

**.QA INFUSION AMPOULES**

Infusion ampoules.

**.QB INFUSION DRY AMPOULES**

Infusion dry ampoules. Ampoules for infusion containing powders for reconstitution before use.

**.QC INFUSION VIALS/BOTTLES**

Infusion vials or bottles.

**.QD INFUSION DRY VIALS/BOTTLES**

Infusion dry vials or bottles. Vials or bottles for infusion containing powders for reconstitution before use.

**.QE INFUSION BAGS**

Bags containing infusion liquids.

**.QF INFUSION CARTRIDGES**

Cartridges for infusion.

**QF INFUSION CARTRIDGES**

Cartridges for infusion.

**.QS DIALYSIS IRRIGATION AND PERFUSION SOLUTIONS**

Dialysis/irrigation/perfusion solutions are in MQS. Powders which are reconstituted for use in dialysis machines are in MEK.

**.QY OTHER INFUSIONS**

Other special infusions. Includes pre-filled syringes which are specifically stated to be for addition to bags/bottles for infusion as well as infusion bags containing dry powder for reconstitution. Also includes infusions administered into the cerebrospinal fluid e.g. by intracerebroventricular infusion.

Combination packs which contain multiple infusion forms that are each to be administered separately e.g. an infusion ampoule and an infusion vial, are included here.

**.R. CARTRIDGES/PENS**

**.RA CARTRIDGES**

Cartridges containing multiple doses.

Cartridges with needle units e.g. Tubex (Wyeth Ayerst), Carpuject (Sanofi Winthorp) are considered to be pre-filled syringes and are in .N.

When a cartridge is an integral/fixed part of the injection device and cannot be replaced by the user, it is considered to be a pre-filled disposable injection pen. Such products are classified in .RF or .RG e.g. in the Netherlands Humalog-Humaject is described as a "patroon" (cartridge) although it is considered a pen.

**.RB DRY CARTRIDGES**

Powders, granules or pellets in cartridges with or without diluent. This includes two compartment cartridges, dry powder cartridges and also dry powder vials used to charge cartridges for pensets e.g. Norditropin Penset (Novo Nordisk).

When a cartridge is an integral/fixed part of the injection device and cannot be replaced by the user, it is considered to be a pre-filled disposable injection pen. Such products are classified in .RF or .RG e.g. in the Netherlands Humalog-Humaject is described as a "patroon" (cartridge) although it is considered a pen.

**.RF PRE-FILLED PENS**

Disposable pre-filled pens (e.g. NovoLet), independent of the route of administration, are included here. Empty pen devices and empty needle-free delivery systems are classified in .ZY.

Pre-filled, disposable needle-free drug delivery systems are also classified here.

Disposable, pre-filled autoinjectors are classified in .NH (Pre-filled Autoinjectors).

Pre-filled manual self-injectors are classified in .NJ.

**.ZK GEL AND COLLOID DRESSINGS**

Dressings which absorb exudates from wounds. Includes dressings both with and without substance.

**.ZP BONE CEMENTS WITHOUT SUBSTANCE**

Bone cements which do not contain a pharmacologically active substance.

Bone cements containing x-ray contrast media but no other active substance are included here.

**.ZQ MECHANICAL PESSARIES WITHOUT SUBSTANCE**

Mechanical pessaries without substance. These are mechanical devices used to prevent prolapse of the womb not vaginal suppositories. Also included are vaginal contraceptive diaphragms, caps and female condoms without substance.

**.ZT DIAGNOSTIC STICKS**

Diagnostic sticks.

**.ZV DIAGNOSTIC TEST EXCLUDING STICKS**

Diagnostic tests excluding sticks. This class will be used only when no specific code to describe the form exists. For example, if the test is presents as a solution in a vial for subcutaneous use, it will be in FPE.

**.ZY. OTHER MEDICAL AIDS**

Other medical aids. Included are Plaster of Paris (Gypsum), first aid kits, stomacare products, condoms, empty syringes, inhaler devices, non-medicated contact lenses, non-medicated tissues and wipes etc. Plaster of Paris, first aid kits, semi-permeable film dressings, stomacare products and male condoms have the first letter M; empty syringes/pens and inhaler devices have the first letter V.

Packs containing medical aids together with another form, containing the active pharmaceutical substance, are classified according to the form containing the active substance, and not as a combination pack. Form example, a pack consisting of an inhaler device and a metered-dose pressurised inhaler, containing a B2-stimulant, is classified RHP. Similarly, a pack with an insulin pen together with a vial containing a retard insulin preparation for subcutaneous injection is classified GPE. Disposable pre-filled insulin pens are classified in .NE.

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| **SECOND AND THIRD LETTER VALID FIRST LETTERS** | | **A** | **B** | **D** | **E** | **F** | **G** | **H** | **I** | **J** | **K** | **M** | **N** | **P** | **Q** | **R** | **T** | **V** | **Z** |
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| **.N.** | **PRE-FILLED SYRINGES** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NA | PRE-FILLED SYRINGES |  |  |  |  | F | G |  |  |  |  | M | N |  | Q |  |  |  |  |
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| .NB | DRY PRE-FILLED SYRINGES |  |  |  |  | F | G |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NC | I V PRE-FILLED SYRINGES |  |  |  |  | F |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| .ND | I M PRE-FILLED SYRINGES |  |  |  |  | F | G |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NE | S C PRE-FILLED SYRINGES |  |  |  |  | F | G |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NF | INTRADERMAL PRE-FILLED SYRINGES |  |  |  |  | F |  |  |  |  |  | M |  |  |  |  |  |  |  |
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| .NH | PRE-FILLED AUTOINJECTORS |  |  |  |  | F | G |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NJ | PRE-FILLED MANUAL SELF-INJECTORS |  |  |  |  | F | G |  |  |  |  |  |  |  |  |  |  |  |  |
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| .NS | INSTIL PRE-FILLED SYRINGES |  |  |  |  |  |  |  |  |  |  | M |  |  |  |  |  |  |  |
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| .NY | OTH PRE-FILLED SYRINGES |  |  |  |  | F | G |  |  |  |  | M |  |  |  |  |  |  |  |
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| .NZ | CMB-PCK PRE-FIL SYRINGES |  |  |  |  | F |  |  |  |  |  |  |  |  |  |  |  |  |  |

**F Parenteral Ordinary**

FM Parenteral Ordinary Ampoules

FMA Parenteral Ordinary Ampoules

FMB Parenteral Ordinary Dry Ampoules

FMC Parenteral Ordinary I V Ampoules

FMD Parenteral Ordinary I M Ampoules

FME Parenteral Ordinary S C Ampoules

FMF Parenteral Ordinary Intradermal Ampoules

FMY Parenteral Ordinary Other Ampoules

FMZ Parenteral Ordinary Combination Pack Ampoules

FN Parenteral Ordinary Pre-Filled Syringes

FNA Parenteral Ordinary Pre-Filled Syringes

FNB Parenteral Ordinary Dry Pre-Filled Syringes

FNC Parenteral Ordinary I V Pre-Filled Syringes

FND Parenteral Ordinary I M Pre-Filled Syringes

FNE Parenteral Ordinary S C Pre-Filled Syringes

FNF Parenteral Ordinary Intradermal Pre-Filled Syringes

FNH Parenteral Ordinary Pre-Filled Autoinjectors

FNJ Parenteral Ordinary Pre-Filled Manual Self Injectors

FNY Parenteral Ordinary Other Pre-Filled Syringes

FNZ Parenteral Ordinary Combination Pack Pre-Filled Syringes

FP Parenteral Ordinary Vials

FPA Parenteral Ordinary Vials

FPB Parenteral Ordinary Dry Vials

FPC Parenteral Ordinary I V Vials

FPD Parenteral Ordinary I M Vials

FPE Parenteral Ordinary S C Vials

FPF Parenteral Ordinary Intradermal Vials

FPY Parenteral Ordinary Other Vials

FPZ Parenteral Ordinary Combination Pack Vials

FQ Parenteral Ordinary Infusions

FQA Parenteral Ordinary Infusion Ampoules

FQB Parenteral Ordinary Infusion Dry Ampoules

FQC Parenteral Ordinary Infusion Vials/Bottles

FQD Parenteral Ordinary Infusion Dry Vials/Bottles

FQE Parenteral Ordinary Infusion Bags

FQF Parenteral Ordinary Infusion Cartridges

FQY Parenteral Ordinary Other Infusions

FR Parenteral Ordinary Cartridges/Pens

FRA Parenteral Ordinary Cartridges

FRB Parenteral Ordinary Dry Cartridges

FRF Parenteral Ordinary Pre-Filled Pens

FRG Parenteral Ordinary Dry Pre-Filled Pens

FRP Parenteral Ordinary Unit Dose Cartridges

**G Parenteral Retard**

GM Parenteral Retard Ampoules

GMA Parenteral Retard Ampoules

GMB Parenteral Retard Dry Ampoules

GMD Parenteral Retard I M Ampoules

GME Parenteral Retard S C Ampoules

GMY Parenteral Retard Other Ampoules

GN Parenteral Retard Pre-Filled Syringes

GNA Parenteral Retard Pre-Filled Syringes

GNB Parenteral Retard Dry Pre-Filled Syringes

GND Parenteral Retard I M Pre-Filled Syringes

GNE Parenteral Retard S C Pre-Filled Syringes

GNH Parenteral Retard Pre-Filled Autoinjectors

GNJ Parenteral Retard Pre-Filled Manual Self Injectors

GNY Parenteral Retard Other Pre-Filled Syringes

GP Parenteral Retard Vials

GPA Parenteral Retard Vials

GPB Parenteral Retard Dry Vials

GPD Parenteral Retard I M Vials

GPE Parenteral Retard S C Vials

GPY Parenteral Retard Other Vials

GR Parenteral Retard Cartridges/Pens

GRA Parenteral Retard Cartridges

GRF Parenteral Retard Pre-Filled Pens

GRG Parenteral Retard Dry Pre-Filled Pens

GRP Parenteral Retard Unit Dose Cartridges

GY Parenteral Retard Other Special Forms

GYV Parenteral Retard Implants