HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Interchangeable Medicines

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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1 BACKGROUND

1.1 About the Act

The Health (Pricing and Supply of Medical Goods) Act 2013 was enacted on 28 May 2013. The Act provides for the introduction of a system of generic substitution and reference pricing for medicinal products (medicines). The main objectives of the Act are as follows:

1 To establish a list of groups of interchangeable medicines which can be substituted for each other in order to enable savings to be made for patients or the State, or both, where the lower priced medicines are supplied. This is often referred to as generic substitution.
2 To establish a list of drugs, medicines and medical and surgical appliances which can be supplied under section 59 of the Health Act, 1970.
3 To establish mechanisms to set the prices of such drugs, medicines and medical and surgical appliances where they are so supplied. This is referred to as the reference price.

The Health Products Regulatory Authority (HPRA) is responsible for the establishment of a list of groups of interchangeable medicines which may be substituted for each other (point 1 above). The HPRA does not have a role in the other elements of the legislation such as pricing.

The Act permits pharmacists to substitute medicinal products which have been designated as interchangeable by the HPRA; this is commonly known as 'generic substitution'. Previously, when a specific brand of medicine was prescribed for a patient, a pharmacist could only supply that particular brand, even when less expensive versions of the same medicine were available.

Reference pricing involves the setting of a common reimbursement price, or reference price, for a group of interchangeable medicines. Patients will not face any additional costs for products priced at or below the reference price. If patients would like to receive a particular brand of medicine that costs more than the reference price then they will have to pay the difference between the reference price and the cost of the brand-named medicine. In cases where substitution is prohibited for clinical reasons, patients will not face any additional costs if the prescribed product costs more than the reference price. The HPRA has no role in reimbursement or in setting prices of medicines. This is the responsibility of the Health Service Executive (HSE).

Generic substitution, coupled with reference pricing, provides patients with an incentive to opt for the lowest cost medicine that is available, without imposing any additional costs on patients.

1.2 Reference and generic medicines

Under European and Irish legislation, all medicines must be authorised before being marketed. Medicines marketed in Ireland must be authorised by the HPRA or the European Commission. Information on authorised medicines is available from the HPRA website at www.hpra.ie.

Medicines are classified into two main types, reference and generic medicines, depending on the data that are submitted in applications for authorisation. The data requirements for these applications are harmonised in law across the European Community and the definitions of these medicines are outlined in EU legislation (Directive 2001/83/EC).

A **reference** medicine is one that has been authorised following the submission of a dossier containing full pharmaceutical, pre-clinical and clinical trial data. Such medicines are also referred to as branded, originator or proprietary medicines. Following authorisation, reference medicines are entitled to a ten-year period of market protection prior to the introduction of a generic medicine.

A **generic** medicine contains the same quantity of active substance and is used in the same dose to treat the same condition as a reference medicine. It meets the same standards of quality and safety and has the same effect as a reference medicine. The data submitted for authorisation of a generic medicine are reduced. The dossier contains full pharmaceutical data; the clinical data may include a study demonstrating bioequivalence with the reference product. In certain circumstances, bioequivalence data are not required, and a waiver of bioequivalence is submitted.

The requirements for bioequivalence data are harmonised across the European Community. A bioequivalence study is performed in healthy volunteers. The volunteers receive single doses of the reference and generic medicine and blood samples are taken to determine the handling of the medicines by the body. The reference and generic medicines are considered bioequivalent when they produce the same plasma concentration of active substance in the body when tested.

When a generic medicine is demonstrated to be bioequivalent to a reference medicine, the benefits and risks of both medicines are considered the same and the generic medicine can usually be substituted for the reference medicine. In cases where, for clinical reasons, the prescribing physician does not wish the branded interchangeable medicine to be substituted, they write ‘do not substitute’ on the prescription and the dispensing pharmacist dispenses the specific medicine prescribed.

2 CRITERIA FOR INTERCHANGEABLE MEDICINES

The Health (Pricing and Supply of Medical Goods) Act 2013 outlines the circumstances under which medicines are considered interchangeable and where they are considered not interchangeable. The purpose of the legislation is to provide for substitution of medicines that are considered interchangeable so that a pharmacist can dispense a medicine that costs less than the one prescribed. Frequently asked questions on the Health (Pricing and Supply of Medical Goods) Act 2013 are provided in appendix I of this guide.

Interchangeable medicines are those that:

1 Have the same qualitative and quantitative composition in each of their active substances
2 Are in the same pharmaceutical form
3 Have the same route of administration
4 Have not more than two active substances.

The circumstances where medicines are considered not interchangeable include where there are clinically significant differences between medicines or where medicines cannot be safely substituted for other medicines. These criteria are taken into account in the decision-making process conducted by the HPRA. The criteria that are used by the HPRA to determine interchangeability are outlined in the following table.

Table 1: Criteria for interchangeable medicines

CRITERION	TITLE	DESCRIPTION
1	Qualitative and quantitative composition	Qualitative and quantitative composition of active substances must be the same. As outlined in the Directive 2001/83/EC, Article 10.2, in the context of generic medicines, the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.
2	Pharmaceutical form	Pharmaceutical form must be the same or similar and suitable for interchangeability. As per Directive 2001/83/EC, in the context of generic medicines, Article 10.2, the various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form e.g. tablets and capsules.
3	Route of administration	Route of administration must be the same.
4	Bioavailability	An authorised generic medicine has demonstrated bioequivalence with the relevant reference medicine

CRITERION	TITLE	DESCRIPTION
		using bioavailability data. Waivers to the provision of bioavailability data are permitted under certain circumstances. Medicines will not be considered interchangeable where there is a difference in bioavailability which is clinically significant in terms of efficacy. Guidance on bioequivalence is listed at the end of this guide[1234].
5	Number of active substances	Only medicines with two or less active substances can be included.
6	Medical device	Products where the medical device for administration of the medicine, if any, has significantly different instructions for use will not be considered interchangeable.
7	Biologicals	Biological medicines are excluded.
8	Safe substitution	Products will not be considered interchangeable if they cannot be safely substituted. This will be decided on a case-by-case basis. Examples include some narrow therapeutic range medicines: defined as minimal difference between benefit and risk. Some modified release[2] or transdermal products[4]: with different posology.

[1] Guideline of the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1/Corr**)
[2] Modified Release Oral and Transdermal Dosage forms: sections I and II (CPMP/QWP/604/96, CPMP/EWP/280/96)
[3] Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) (CPMP/EWP/4151/00 rev 1)
[4] Clinical Requirements for Locally Applied, Locally Acting Products containing Known Constituents (CPMP/EWP/239/95)

3 LIST OF INTERCHANGEABLE MEDICINES

Under the Act, the HPRA is required to establish, publish and maintain a 'List of Interchangeable Medicines' (IC list). Medicines that are considered interchangeable are grouped together according to their active substance, strength (dose) and pharmaceutical form.

The following conditions apply to the list of interchangeable medicines:

- In placing a medicine on the list of interchangeable medicines, the HPRA is confirming that it is interchangeable with other medicines in the same group on the list. A summary of product characteristics (SmPC) for each medicine on the list is available and can be consulted by healthcare professionals in order to determine any potential differences in indications, excipients, pack sizes or product descriptions amongst medicines within a group on the list.
- Interchangeable medicines are presented in groups on the list. Medicines containing the same active substance in the same strength, in the same pharmaceutical form, and with the same route of administration are included in a single group.
- The list includes only medicines that are the subject of a marketing authorisation. However, not all of these medicines may be marketed in Ireland.
- The requirement for interchangeable medicines to have a reimbursement code and/or to be currently marketed in order to have a reimbursement code, relates only to the setting of reference pricing (Part 5 of the Act), which is under the remit of the HSE, not the HPRA. Accordingly, any concerns or comments regarding requirements for reimbursement codes and/or marketing status in relation to reimbursement, must be addressed to the HSE.
- Parallel-imported products of nationally-authorised products, provided that the importer obtains a parallel product authorisation (PPA) to market the product in Ireland and provided that they fulfil the requisite provisions mentioned in Table 1 above, are included in the list as they are deemed therapeutically equivalent to a reference product(s) already authorised in Ireland. This is inherent given that the definition of 'authorisation holder', as set out in section 2 of the Act, includes a holder of a parallel import licence.
- Centrally authorised products that are parallel-distributed are not included in the list as the marketing authorisations for centrally-authorised products are already valid in all Member States of the European Union and the only changes permitted for parallel-distributed products are changes in the language of the product information as assessed and approved by the European Medicines Agency (EMA).
- Dual pack registration (DPR) products are considered to be included in the list if the relevant Irish market product is included in the list, as a DPR product is equivalent to the Irish market product in all respects and carries the same marketing authorisation number as the Irish market product.
- Given that the primary objective of the legislation is to enable savings to be made for patients and/or the HSE, non-prescription or over-the-counter (OTC) medicines that are not reimbursed by the HSE are not included on interchangeable lists. An exception to this rule may exist where a marketing authorisation has a range of pack sizes, some of which

are prescription-only pack sizes and others of which are OTC pack sizes. However, inclusion of such product(s) on the list will be contingent on the active substance(s) in question, the authorised indications, and the authorised pack sizes.
- Inclusion on the list does not override the prescriber's discretion to exempt a medicine from substitution for clinical reasons. In such instances, the prescriber indicates 'do not substitute' on the prescription beside the name of the medicine.

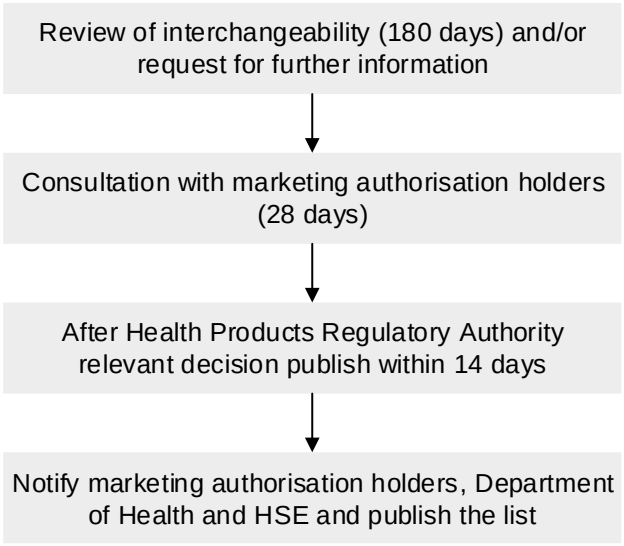
4 PROCESS FOR INCLUSION ON THE LIST OF INTERCHANGEABLE MEDICINES

4.1 The development of the list of interchangeable medicines

The HPRA may, on its own initiative, or at the request of the Minister for Health or the HSE, add a medicine or a group of medicines to the list of interchangeable medicines. As the purpose of the Act is to contain the costs of medicines, the Department of Health asked the HPRA to prioritise the review of the interchangeability of active substances contained in medicines that will achieve the greatest savings to the State and patients. Details of ongoing and completed consultations on medicines may be found on the HPRA website.
Other substances may be reviewed by the HPRA, on its own initiative or at the request of the Minister for Health or the HSE, for example substances contained in medicines that are in short supply.

Following review using the interchangeability criteria, the HPRA makes a proposal regarding the addition of a medicine or a group of medicines to the list; this is referred to in the Act as a proposal for a 'relevant decision'. The proposal for a relevant decision is notified to the marketing authorisation holders of the medicines proposed to be added to the list with the HPRA quoting an interchangeable list code for list identification purposes. Marketing authorisation holders have 28 days to submit written comments on the proposed relevant decision. Following completion of the 28 day consultation period, the HPRA reviews any comments received and makes its decision on whether or not to proceed with the addition to the list (referred to in the legislation as a 'relevant decision'). Once this decision is made the HPRA must give notice in writing, together with its reasons for making that relevant decision, within 14 days. If the decision is to proceed with the addition of a medicine or a group of medicines to the list, the marketing authorisation holders and the HSE are notified and the list is published on the website (see Figure 1).

Figure 1: Decision on interchangeable status



~~Figure 1: Decision on interchangeable status~~

Where modifications to the proposal for a relevant decision are made, a further 28-day consultation will take place. The HPRA may also decide not to proceed with the relevant decision, in which case the marketing authorisation holders are notified and the list is not updated.

It is also possible for the marketing authorisation holder to make an application to have a medicine added to the list of interchangeable medicines or to add a group of medicines to the list. The maximum timeline for review of applications is 180 days.

4.2 Amendments to the list of interchangeable medicines

Marketing authorisation holders can apply to have newly authorised medicines included in a group on the list. The decision-making process for such applications is the same as that set out in Figure 1 above.

Immaterial changes to the list will not require consultation with the marketing authorisation holders. Examples of immaterial changes include, but are not limited to, typographical errors, removal of products that are no longer authorised, a change in the name of a marketing authorisation holder which is not subject to a marketing authorisation transfer, a change in the invented name of the medicinal product, a change in the name of the active substance to comply with World Health Organisation (WHO) nomenclature or a change in the

interchangeable list code. The updated list will be published on the HPRA website, but no prior notification will take place for such changes.

The HPRA can remove an interchangeable medicine from a group or remove a group from the list on a number of grounds including safety concerns. A medicine that is no longer authorised or no longer fulfils the definition of a medicine will be removed from the list administratively. Marketing authorisation holders and the HSE will be notified of a decision to remove a medicine from the list. If a medicine is suspended or withdrawn for quality or safety reasons, and is thereby removed from the list, pharmacists and prescribers will be notified in accordance with existing HPRA procedures.

The list is reviewed and updated biannually ~~to take account of the creation of new groups of interchangeable medicines and changes to existing groups. Removal of products that are no longer authorised, product name changes etc. are carried out during the review. The updated list will be available on the HPRA website.~~

~~The biannual review cycle is used~~ to add newly-authorised products to existing groups and ~~also~~ to introduce new groups to the list. ~~Such c~~Changes to existing groups will require a consultation with MAHs and the decision~~-~~-making process will be the same as that set out in Figure 1 above. The updated list will be available on the HPRA website.

4.3 Appeals

It is possible to appeal the relevant decision made by the HPRA to the High Court within 30 days of notification of the decision. It should be noted that an appeal does not suspend the implementation of the decision i.e. the updating and publication of the list.

4.4 Further Information

The Health (Pricing and Supply of Medical Goods) Act 2013 is available on the Oireachtas website, www.oireachtas.ie.

Queries on updates to the list of interchangeable medicines ~~on the list of interchangeable medicines can~~should be sent to ICqueries@hpra.ie. These queries will be reviewed on a case-by-case basis and the HPRA will respond within 28 days from the date of receipt of the query.

APPENDIX 1 FREQUENTLY ASKED QUESTIONS

A Status, main elements and purpose of Act

Q1 What is the status of the Act?

The Health (Pricing and Supply of Medical Goods) Act 2013 was enacted on 28 May 2013 and commenced on 24 June 2013.

Q2 What are the main elements of the Act?

The Act provides for the introduction of a system of generic substitution and reference pricing for interchangeable medicines. The Health (Pricing and Supply of Medical Goods) Act 2013 is available on the Oireachtas website.

Q3 What is the purpose of the Act?

The main objective of this Act is to ensure value for money in the supply to patients of medicines and other prescribed items under Section 59 of the Health Act 1970.

B Generic substitution

Q4 What is generic substitution?

Generic substitution, under this Act, permits pharmacists to substitute medicines which have been designated as interchangeable by the HPRA. Previously, when a specific brand of medicine was prescribed for a patient, a pharmacist could only supply that specific brand.

Q5 What is a generic medicine?

A generic medicine is a medicine that is similar to an originator/proprietary medicine. It has the same active substance(s) as the brand-named medicine and is made to the same standard to make sure it is safe and effective.

Q6 Why do generic medicines look different?

Generic versions of a medicine may have different colours, flavours or combinations of non-active substances compared to the originator/proprietary medicine. A generic medicine may also be in a different form (e.g. tablet or capsule), shape or size and come in a different box, package or bottle. None of these differences affect the way the medicine works.

Q7 Are generic medicines safe and effective?

Yes, a generic medicine must meet exactly the same standards of quality and safety and have the same effect as the originator/proprietary medicine.

Q8 Does every medicine have generic versions?

Not every originator/proprietary medicine has a generic medicine version. When new medicines are first made they are protected under European law by patents for a number of years. The patent protects the company that developed the medicine and prevents other companies from selling the medicine. When the patent expires, another pharmaceutical company can apply for authorisations to market generic versions of the medicine.

Q9 What is an interchangeable medicine?

Interchangeable medicines contain the same active substance in the same strength, have similar pharmaceutical forms and have the same route of administration.

Q10 Who decides if a medicine is interchangeable?

The HPRA is responsible, subject to the qualifying criteria set out in the legislation, for deciding if a medicine can be interchanged with the originator/proprietary medicine. If the HPRA agrees that it is acceptable to interchange the medicine, it will publish this on a 'List of Interchangeable Medicines'. Medicines on the list may be substituted for each other to enable savings to be made for patients or the State, or both, where lower priced medicines are supplied; this is known as generic substitution.

Q11 Can every medicine be substituted?

No, the HPRA will only add a medicine to the list of interchangeable medicines if it meets all the qualifying criteria and can be safely substituted for each of the medicines which fall within a group of interchangeable medicines.

Occasionally circumstances may arise where, due to an individual patient issue or characteristic, it may not be advisable to switch between different versions of a medicine even if the medicine is included in a group of interchangeable medicines. When this arises a prescriber will be able to indicate on a prescription that substitution should not take place. A pharmacist will then dispense the medicine indicated on the prescription.

Q12 Is there a list of interchangeable medicines?

The HPRA has established a list of interchangeable medicines which is currently published on our homepage. The HPRA will be adding further active substances to the list on a continual basis. Information relating to ongoing and completed consultations can also be found on our homepage.

C Process and timelines

Q13 Who decides which medicines should be included on the list?

The Act permits the HPRA to include medicines on the list, or the Minister for Health or the Health Service Executive (HSE) may request the HPRA to do so. It is also possible for a marketing authorisation holder to apply to have a medicine included on the list, but as the objective of the legislation is to deliver savings to patients and the State, the medicines that result in the greatest cost were reviewed first, having due regard to the terms of the legislation.

Q14 When was the first list published?

The initial list was published by the HPRA on 7 August 2013 and included 96 atorvastatin products within four separate groups. Other medicines have been added to the list on an ongoing basis following consultation with the various MAHs. The process involves consultation with all concerned MAHs on the proposed groups of interchangeable medicines and MAHs have 28 days in which to comment. The HPRA reviews comments received and publishes the revised list within 14 days of making its relevant decision.

Q15 Which medicines are included on the list?

The legislation was introduced to ensure value for money in the supply of medicines. Therefore, the medicines that were reviewed first were those that cost the most to the patient or the State. The HPRA was asked by the Department of Health to prioritise review of the classes of medicines that resulted in the greatest costs. Details of ongoing and completed consultations on medicines may be found on the HPRA website.

Other substances may be reviewed by the HPRA, on its own initiative or at the request of the Minister for Health or the HSE, for example, substances contained in medicines that are in short supply.

Q16 How is the list presented?

Interchangeable medicines are presented in groups on the list. Medicines containing the same active ingredient in the same strength, having similar pharmaceutical forms and with the same route of administration, are included in a single group. Only authorised medicines

are included on the list. In addition, a link to the SmPC and Human Medicines Product List on the HPRA website is provided for each medicine; this may be consulted by healthcare professionals, as necessary.

Q17 Can a single group on the list contain two pharmaceutical forms?

Yes. Depending on the active substance in question and the authorised generic medicines, a group on a list may contain two or more pharmaceutical forms e.g. immediate-release capsules and tablets. Article 10(2) of Directive 2001/83/EC states that the various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form for the purposes of a generic application. Therefore, different pharmaceutical forms could be included on the list if they can be safely substituted. This is decided on a case-by-case basis.

Q18 What is the timeline for review of medicines?

If the HPRA receives an application for inclusion of a medicine on the list, it has a maximum of 180 days to review the medicine and make a proposed relevant decision to add (or refuse to add) the medicine to an interchangeable group. During this 180 day timeframe, a consultation process is initiated in relation to the proposed decision and the marketing authorisation holders have 28 days to comment in writing. The HPRA reviews and considers any comments received during the consultation period prior to making the relevant decision in relation to the application. The MAHs are informed in writing of the relevant decision, as soon as is practicable after making the decision (and not later than 14 days after the decision is made). As appropriate, the list is updated within 14 days of making the relevant decision and published on the HPRA website.

Q19 How often is the list updated?

The list is reviewed and, if necessary, updated biannually to take account of the creation of new groups of interchangeable medicines and changes to existing groups. Any changes that require consultation (addition of products(s) or creation of a new group within a published list) are subject to the consultation process. Changes, such as product transfers, name changes etc., are carried out as they arise ~~or else during the biannual review~~. Please refer to www.hpra.ie for further details.

Q20 Are there fees for inclusion on the list?

The Act permits the HPRA to charge fees. This matter is currently under discussion and marketing authorisation holders will be advised when a decision is made.

Q21 What happens if a medicine on the list is out of stock?

The HPRA has a process for marketing authorisation holders to notify out-of-stock situations. The circumstances of the out-of-stock situation are considered and a decision is taken on

whether the medicine should be removed from the list. The marketing authorisation holder is notified if a medicine is removed from the list.

Q22 What happens if a medicine is removed from the list?

If a medicine is removed from the list for safety reasons, healthcare professionals and the marketing authorisation holder are notified in the usual way. If a medicine is no longer authorised, it will automatically be removed from the list ~~at the next update~~.

Q23 Does the list contain medicines that are not currently marketed?

The list of interchangeable medicines refers to medicines that are the subject of a marketing authorisation. As it is the prerogative of marketing authorisation holders to market or not to market an authorised medicine, the list may contain medicines that are not marketed.

Q24 Are any classes of medicines excluded?

The criteria for interchangeable medicines are outlined in the Act. Biological medicines and medicines with more than two active substances are excluded. No other classes of medicines are excluded and medicines are reviewed on a case-by-case basis.

Q25 Are parallel imports included?

The definition of an 'authorisation holder' in section 2 of the Act includes a holder of a parallel product authorisation. Therefore, parallel imported products of nationally authorised products are listed in a group, provided that the nationally authorised reference product(s) fulfils the criteria for interchangeable medicines.

Dual pack registration (DPR) holders do not fall under the definition of an 'authorisation holder' in section 2 of the Act as these are registrations rather than marketing authorisations. Notwithstanding this, DPRs are considered to be included in the list if the relevant Irish market product is included in the list as a DPR product is equivalent to the Irish market product in all respects and carries the same product authorisation number as the Irish market product.

Q26 Are non-prescription/over-the-counter (OTC) medicines included?

Given that the primary objective of the legislation is to enable savings to be made for patients and the HSE, non-prescription/OTC medicines that are not reimbursed by the HSE are not included on interchangeable lists. An exception to this rule may exist where a marketing authorisation covers a range of pack sizes, some of which are prescription-only pack sizes and others OTC pack sizes. However, inclusion of such product(s) on the list is contingent on the active substance(s) in question, the authorised indications, and the authorised pack sizes.

Q27 Do authorised generic medicines which have been deemed to be bioequivalent to a reference medicine automatically qualify as being interchangeable?

The criteria that are used to determine whether medicines are interchangeable are those outlined in the legislation. Unless there is a safety concern which precludes creation of a group of interchangeable medicines or the addition of a medicine to a group of interchangeable medicines, the HPRA can tentatively state that authorised generic medicines, which have been deemed to be bioequivalent to the reference medicine, will qualify as being interchangeable.

Q28 Is there a process to appeal a HPRA decision?

During the consultation process written comments on a proposed group of interchangeable medicines may be submitted to the HPRA by the marketing authorisation holders with medicines listed in the proposed group. Following the HPRA's decision, the Act permits an appeal but this will not delay publication of the list.

Q29 Is the originator company notified when its product is placed on the list?

Marketing authorisation holders are only notified if they have an authorised medicine which is on the list.

Q30 Are newly authorised products automatically added to the appropriate list of interchangeable medicines?

A company may apply to have its medicine added to an existing IC list or it may wait until the biannual review cycle when, if the medicinal product meets the interchangeability criteria, it will be added and the consultation process undertaken.

D Technical

Q31 Are unauthorised medicines included on the list?

No, only authorised medicines can be included on the list.

Q32 Can the list be accessed from the HPRA Human Medicines Products List without going into the new interchangeable section?

Yes, the list can be accessed from the HPRA Human Medicines Products List web page by clicking on the hyperlink provided on the page for each medicine.

Q33 Does the list include ATC codes?

The ATC code can be found in section 5.1 of the SmPC, which is available for each medicine on the list.

Q34 Can the entire list be downloaded as XML or CSV?

The HPRA provides the list as both XML and CSV files. The list is updated regularly, so stakeholders are advised to register for HPRA web alerts.

Q35 Does the HPRA display pricing information?

No, the HPRA does not display pricing information as this is not within our remit. Pricing and reimbursement are the responsibility of the HSE.

Q36 How does the HPRA communicate with the HSE?

The HPRA provides information to the HSE on medicines included on the list of interchangeable medicines.

Please send any further queries to ICqueries@hpra.ie.