Proposed Model
for Reference Pricing and
Generic Substitution

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1. Overview

Demographic changes over the next decade will have a significant impact on the demand for and the delivery of health care in Ireland. Pharmaceutical expenditure accounts for a large proportion of overall health care expenditure. In 2008 the Health Service Executive paid for approximately 65 million prescription items at a cost of over €1.9 billion. As a result of demographic changes and prescribing trends, the number of prescription items is estimated to increase to 105 million by 2021 at cost of €2.4 billion[1]. The current system is unsustainable. To ensure that patients can continue to access innovative and affordable medicines, new pricing and reimbursement approaches are required, along with changes in prescribing practices.

Many countries, in both Europe and elsewhere, already have systems of reference pricing and substitution of interchangeable medicines in place. The promotion of competitive markets for generic medicines is seen as a key element in the sustainable provision of medicines. In 2009 the European Commission adopted the final report on its competition inquiry into the pharmaceutical sector[2] and invited Member States to introduce measures to support the speedy uptake of generic medicines and improved price competition.

It is in this context that the Government has approved the Minister for Health and Children's proposal to introduce a system of reference pricing combined with generic substitution.

Currently when a branded medicine is prescribed that specific medicine must be dispensed. Under the proposed system pharmacists will be able to substitute a designated interchangeable medicine. In a reference price system the State determines a maximum amount, known as the reference price, which is the basis for reimbursement for a group of interchangeable medicines. Any difference between this reimbursement price and the actual price, if greater, must be paid by the patient. Patients can avoid any potential co-payments by opting for a less expensive interchangeable medicine.

[1] Layte, R (Ed.) et al, *Projecting the Impact of Demographic Change on the Demand for and Delivery of Health Care in Ireland*, ESRI Research Series, No 13, October 2009.
[2] European Commission, Competition DG, *Pharmaceutical Sector Inquiry Final Report*, July 2009.

The Minister appointed Mr. Mark Moran to chair a joint Department of Health and Children/Health Service Executive working group, which commenced its work in early November 2009. A list of participants and the process undertaken by the group are provided in appendix A. The remit of the group was to devise an appropriate system of interchangeable medicines and a reference price system for Ireland taking into account international experience of such systems. An overview of the application of reference pricing and generic substitution in other countries is provided in appendix B.

The following factors are widely accepted internationally as being essential for a reference price system:

- Medicine interchangeability (sometimes restricted to the more limited approach known as "generic substitution");
- The involvement of participants (patients, carers, prescribers, pharmacists, industry, etc) from an early stage;
- A comprehensive patient communications strategy to ensure acceptance and understanding of the new system;
- A sufficient number of competing pharmaceuticals with low barriers to entry for interchangeable medicines;
- Price competition for interchangeable medicines;
- Patient price sensitivity.

This report presents the working group's assessment of the most appropriate reference price system for Ireland and identifies the legal and administrative changes required to give it effect. The working group met with key stakeholders and received a number of written submissions. Information on the consultation process is provided at appendix C. Ongoing consultation is planned as part of the legislative and implementation processes.

Section two presents a system for interchangeable medicines in Ireland. Section three deals with the reference pricing system. Section four provides an implementation plan for the introduction of the reference price system and section five provides financial analysis.

2. Interchangeable Medicines

Existing legislation in Ireland requires that the medicine dispensed is exactly what is written on the prescription[3]. In many countries, medicines that have been designated as interchangeable can be substituted by the pharmacist. This means that a designated interchangeable medicine, with the same quality and clinical efficacy, can be dispensed.

Appropriate interchangeability of medicines enables flexible dispensing, requiring less stock to be held in pharmacies. It also promotes price competition between manufacturers of interchangeable medicines, providing potential savings for both the State and patients. However, some medicines are not suitable for substitution, so a system of control and oversight is required.

The group recommends the introduction of legislation to enable interchangeability of medicines which will establish appropriate systems and structures and define roles and responsibilities relating to interchangeability of medicines.

To facilitate the inclusion of new generics as soon as they are available the HSE, which currently administers the list of reimbursable medicines, should administer the list of interchangeable medicines.

The key features of the recommended system are:

- The Minister for Health and Children should be responsible for policy matters relating to the interchangeability of medicines;

- The HSE should be responsible for implementing and operating the systems relating to interchangeability of medicines;

- A Committee on Interchangeable Medicines should be established. The Minister of Health and Children should appoint the members of the committee and sets its terms of reference. This will ensure that the Minister will retain policy control over what types of medicines may be

[3] Art 5(1) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 [substituted by Art 6 of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008]

designated as interchangeable (e.g. generic or therapeutic equivalents). Detailed draft terms of reference and procedures for the committee have been prepared.

- The Minister should initially request the Committee on Interchangeable Medicines to limit interchangeability to ATC level 5[4], i.e. medicines containing the same active ingredients.

- The committee should approve and keep under review criteria for interchangeability and should provide guidance to the HSE on matters relating to interchangeability. The committee may also make recommendations in relation to the grounds for clinical exemptions from substitution. Draft criteria for interchangeability are provided in appendix D.

- The criteria for interchangeability should be developed having regard to:
    - the overall health needs of the population;
    - the availability and suitability of existing medicines to be interchanged;
    - the clinical benefits and risks of the pharmaceuticals which are proposed to be interchangeable;
    - the cost to the State and patients; and
    - international best practice.

- The HSE should designate medicines as interchangeable, having regard to the criteria, guidance and recommendations of the Committee on Interchangeable Medicines.

- An appeals process will be established.

- The list of interchangeable medicines, as approved by the CEO of the HSE, should be updated and published no more than four times per annum.

- The list of interchangeable medicines should apply to medicines dispensed in hospitals, medicines provided under the GMS and community drugs

[4] ATC 5 defines a single active ingredient or a fixed combination of active ingredients within the anatomic therapeutic chemical classification system of the World Health Organisation (e.g. C10AA05 is the ATC code for all medicines containing the single active ingredient atorvastatin).

schemes and medicines provided to private patients[5].

- Once a category of interchangeable medicines has been approved, then any medicine within that category may be interchanged with another in that category.

- Only interchangeable medicines on this list can be substituted.

- If a pharmacist is substituting an interchangeable medicine, he or she must inform the patient[6].

- When an interchangeable medicine has been prescribed and a less expensive interchangeable medicine is available, the pharmacist must inform the patient of the availability of the less expensive interchangeable medicine[7].

- The patient should decide whether or not to opt for a less expensive interchangeable medicine[8].

- Some patients will require a particular brand of medicine for clinical reasons. In these instances prescribers may object to substitution by including an specified exemption code on the prescription[9]. This will enable the HSE to monitor the usage of exemptions by prescribers.

The successful introduction of a system of interchangeable medicines will require comprehensive communication with the users of such medicines and the public at large. The core elements of a communications strategy are outlined in appendix E.

[5] All Irish residents are eligible for either the GMS Scheme or the Drugs Payment Scheme.
[6] Hospitals should have a suitable governance structure in place to facilitate the appropriate use of interchangeable medicines.
[7] See footnote 6.
[8] See footnote 6.
[9] In Sweden in 2006 prescribers objected to substitution in 2.5% of cases, http://ppri.oebig.at/Downloads/Results/Sweden_PPRI_2007.pdf

3. Reference Pricing System

When a reference price is set for a group of medicines, that is the price reimbursed by the State unless there is a clinical reason why a patient must receive a product with a higher price. Patients can avoid co-payments if a less expensive medicine within a reference group can be substituted instead of the higher cost medicine.

The key features of the recommended reference pricing system are:

- The HSE may select interchangeable medicines for reference groups and determine reference prices for those groups in accordance with specified criteria, taking into consideration matters including the number of competitors, market size, the public interest, value for money and continuity of supply.

- Some supplier prices may be higher than the reference price.

- The HSE should pay a common reference price for all medicines within a reference group, unless a prescriber has objected to substitution on medical grounds and the product prescribed is priced higher than the reference price.

- If a prescriber has objected to substitution on specified medical grounds, and the product prescribed is priced higher than the reference price, the HSE should reimburse the agreed price of the product for eligible patients (based on prices submitted by suppliers in line with national pricing arrangements).

- The HSE should conduct a market review of all reference groups at least once a year and at most every three months. This will provide flexibility for the HSE to respond to changes in the market, e.g. new entrants, and will not impose an unnecessary administrative burden on the HSE or the pharmaceutical industry.

- The HSE market review should take into account the number of competitors available, market size, the stated intentions of potential entrants, continuity of supply, market prices and any other relevant

information. Following the market review the HSE should then decide whether or not to conduct a price review for each reference group.

- When the HSE decides to conduct a price review, the HSE should request new prices and specific market information from existing suppliers. A published notice on the HSE website will ensure that all potential suppliers are also aware of and can participate in the price review. The HSE should select the new reference price (usually the lowest unless there are concerns about continuity of supply). Suppliers above the reference price may resubmit a lower price. The new reference price should come into effect at a date determined by the HSE.

- When a patient has been prescribed a specific reference medicine and the actual price is higher than the reference price, the patient can opt for a less expensive medicine within that reference group or can pay the difference between the reference price and the actual price (co-payment).

- The HSE should monitor and report on the savings obtained from reference pricing.

The introduction of reference pricing will enhance price competition between suppliers of medicines of the same quality and clinical benefit. Furthermore, it will increase price sensitivity and awareness among patients while providing equitable access to interchangeable medicines based on clinical need.

4. Implementation

The introduction of the model as outlined in the previous sections will require a number of changes.

Legislation and Legal Issues

Existing Irish legislation relating to the dispensing of medicines has been examined, along with legislation relating to interchangeable medicines and reference pricing from other countries.

The core elements required for legislation have been identified. These address:

- the definition of interchangeable medicines;
- the criteria for interchangeability;
- the designation of medicines as interchangeable;
- the establishment, management and publication of a list of interchangeable medicines;
- the authority to dispense interchangeable medicines and liability issues;
- clinical exemptions to substitution;
- the administration of a system of reference pricing by the HSE; and
- the facilitation of co-payments by patients.

Changes to existing regulations are also required to permit the substitution of interchangeable medicines by pharmacists.

A regulatory impact analysis is being prepared which will be published following Government approval of the Bill. Drafting of the legislation will commence shortly.

The European Commission has provided clarification to Member States on the application of Transparency Directive to national pharmaceutical reference pricing systems[10]. The key obligations are:

- The existence of transparent criteria for the establishment of reference groups and reference prices;
- The obligation to provide reasoned decisions including relevant expert opinions underlying these decisions; and
- The availability of effective legal remedies against such decisions.

[10] Application of Directive 89/105/EEC to reference price systems, Transparency Committee, 14 March 2007.

The group believes that its proposals satisfy these requirements.

Communications

Patient education and understanding of the new system was identified by all stakeholders as an essential component in the implementation of the model. A draft communications strategy, which has been costed, is provided in appendix E.

Management and Governance

The HSE has identified 100 potentially interchangeable medicines for the initial introduction of reference pricing, comprising of almost 250 potential interchangeable groups when different product strengths are taken in to account. Additional groups will be added by the HSE over time as interchangeable competitors become available for other medicines.

Resources are required for the administration of the reference price system and supporting the work of the Committee for Interchangeable Medicines. Detailed draft terms of reference, membership and standing orders have been prepared for the Committee.

The HSE estimates a staffing allocation of five whole time equivalents is required to provide:

(i) Secretariat to the Committee on Interchangeable Medicines;

(ii) Preparation of the list of interchangeable medicines and subsequent updates. This workload will decrease after the initial list is prepared;

(iii) Preparation of the initial HSE website tools for patients, i.e. data entry and updating;

(iv) Market reviews and price reviews of reference groups;

(v) Monitoring and reporting on savings.

While it is probable that some of the existing complement of staff would provide such elements as the Secretariat to the Committee, their existing workload would need to be managed through delegation under supervision to other qualified personnel.

Not all of the staff required would need to be pharmacists; pharmaceutical technicians could undertake work such as the preparation of data for the website. If there were sufficient IT enablement for submissions from suppliers, this estimated resource could be adjusted.

ICT development/system changes will be required to:

- facilitate an efficient reference price application process;
- process reference price reimbursement;
- publish and maintain the list of interchangeable medicines; and
- record clinical exceptions and process reimbursement.

ICT developments will be required at both a HSE level and also at the level of GP and community pharmacy systems. Based on discussions with participants, the Group believes that these developments are achievable in a reasonable timeframe.

Detailed costing of ICT developments is dependent on completion of detailed design and relative small changes in design can have a significant impact on costing. However, the ICT enhancements required to implement the proposed system at a HSE level, comprise less than one man year's work, and in context of the proposed savings should not be a major consideration.

It is proposed that clinical exceptions are processed on a prescription by prescription basis as opposed to a system where the population would be registered in advance with the details of their clinical exceptions.

Impacts on Key Stakeholders

The working group acknowledges the impact that substitution of medicines and reference pricing will have on a range of stakeholders. The proposed model aims to deliver value for money for both the State and patients whilst being pragmatic and reasonable. The impacts for patients, prescribers, pharmacists, wholesalers and manufacturers will continue to be a consideration for the Department and the HSE as part of the implementation of any changes.

5. Financial Impact

A recent ESRI report estimated that based on demographic and prescribing trends, the cost to the State of supplying medicines will reach €2.4 billion by 2021. This level of growth in expenditure is unsustainable. To protect the provision of other health care services and to ensure the continued provision of innovative and affordable medicines, greater value for money must be obtained.

The introduction of a system of interchangeable medicines and reference pricing in Ireland can achieve savings and efficiencies in a number of ways:

- reductions in the price paid by the HSE for reference medicines;
- reductions in the prices paid by patients for reference medicines;
- savings to the State when eligible patients opt for less expensive interchangeable medicines that are not included in the reference price system;
- savings for private patients by opting for less expensive interchangeable medicines;
- efficiencies for pharmacists from lower stock costs.

The level of savings from the introduction of reference pricing will depend on a range of factors which include:

- the number and type of medicines included in reference groups;
- the current relative and absolute prices of interchangeable products;
- the market response for each group of interchangeable products;
- the level of exemptions from substitution on clinical grounds; and
- prescribing practices.

The National Centre for Pharmacoeconomics recently analysed the impact on pharmaceutical expenditure arising from generic substitution and reductions in the price of original branded medicines. The analysis was based on prices in July 2009 (i.e. after the reduction in the wholesale and retail mark-ups). Six months data on prescribing volumes were analysed and extrapolated to give estimates for twelve months. The estimated total expenditure in 2009 (by ingredient cost) on the GMS and Drugs Payment Schemes was €325 million for generic and off-patent products.

The top 100 drugs by expenditure which had a generic product available were used for the analysis of generic substitution (the top 100 products by expenditure

represent approximately 80% of the total spend on the schemes). The estimated potential savings, if the lowest cost generic was dispensed would yield in the region of €55.4 million in savings under the GMS scheme and €22.3 million under the Drugs Payment Scheme. In effect, this saving is what would have been achieved in 2009 by 100% substitution of the lowest cost available medicine, or if reimbursement had been limited to the price of the lowest cost available generic medicine.

A separate analysis was conducted by the NCPE to estimate potential savings in 2009 arising from a 40% reduction in the price of off-patent products. The estimated potential savings are approximately €98 million. These estimates do not include potential savings to private patients.

The savings above estimated by the National Centre for Pharmacoeconomics are based on reimbursement prices as of July 2009 and do not reflect the current prices of generic and off-patent products.

The reduction in the prices of certain proprietary medicines in February 2010 has reduced the potential immediate savings from reference pricing for this group of products. Notwithstanding this, the group is satisfied that the introduction of reference pricing will deliver significant ongoing savings.

The potential for savings over the next three to five years is significant as interchangeable medicines become available for high volume medicines. There are approximately 20 such medicines, which would be suitable for inclusion in a reference pricing system, with an ingredient cost of approximately €300 million in 2008. Under the current system a price reduction of 20% is applied once a generic competitor is available on the Irish market and a further price reduction of 15% off the original price is applied 22 months later. Reference pricing of these products is expected to achieve greater reductions in price, at a quicker rate than the current system of off-patent price cuts.

The costs for the State associated with reference pricing will include the upfront costs of implementing a communications strategy and the ongoing administrative costs of the Committee for Interchangeable Medicines and the reference price system. The estimated upfront and ongoing costs of a system of interchangeable medicines and reference pricing are vastly exceeded by the potential savings.

Appendix A: Working Group Participants and Methodology

The working group was asked to examine options and develop a reference pricing system suitable for Ireland, taking into account best international practice. The group met with all key stakeholders and received submissions from a number of stakeholders. Issues raised by stakeholders have been taken into account in the development of a model. The group has also identified the legislative and administrative changes required for the introduction of reference pricing and to permit substitution by pharmacists. The members of the working group, and its various subgroups, included:

Fidelma Browne (HSE)
Patrick Burke (HSE)
Gerald Byrne (HSE)
Dr Joe Clarke (HSE)
Eoin Dunleavy (DOHC)
Deirdre Elliott (HSE)
Shaun Flanagan (HSE)
Nigel Fox (IMB)
Chris Kane (DOHC)
Marita Kinsella (DOHC)
Thomas Monks (DOHC)
Mark Moran (Chair)
Kate Mulvenna (HSE)
Ciara Pidgeon (DOHC)
Eddie Quigley (DOHC)
Lesley Tilson (NCPE)
Cara Usher (NCPE)

Appendix B: International Application of Reference Pricing

Country	Reference Price System	Generic Substitution	Reference Groups	Reference Price	Timing of RP Updates
Cyprus	No	Yes	n/a	n/a	n/a
Luxembourg	No	No	n/a	n/a	n/a
Norway	No	Yes	n/a	n/a	n/a
Sweden	No	Yes	n/a	n/a	n/a
Belgium	Yes	No	ATC 5	Less 30%	Quarterly
Bulgaria	Yes	No	ATC 5 + 4	Lowest	Biannually
Czech	Yes	Yes	ATC 5 + 4	Lowest	2 weeks
Denmark	Yes	Yes	ATC 5	Lowest	2 weeks
Estonia	Yes	Yes	ATC 5	Lowest	Quarterly
Finland	Yes	Yes	ATC 5	Lowest + €1.50	Quarterly
France	Yes	Yes	ATC 5	Lowest	None
Germany	Yes	Yes	ATC 5 + 4	Lowest third	As required
Greece	Yes	Yes	ATC 5	N/A	Quarterly
Hungary	Yes	Yes	ATC 5 + 4	Lowest	Quarterly
Iceland	Yes	Yes	ATC 5	Lowest	N/A
Italy	Yes	Yes	ATC 5	Lowest	Monthly
Latvia	Yes	Yes	ATC 5 + 4 + 3	Lowest	Quarterly
Lithuania	Yes	Yes	ATC 5	Lowest	N/A
Malta	Yes	Yes	ATC 5	Average	No
Netherlands	Yes	Yes	ATC 5 + 4 + 3	Fixed lowest	None
Poland	Yes	Yes	ATC 5 + 4 + 3	Lowest	Biannually
Portugal	Yes	Yes	ATC 5	Highest generic	Quarterly
Romania	Yes	Yes	ATC 5	Lowest	Annually
Slovakia	Yes	Yes	ATC 5 + 4	Lowest	Quarterly
Slovenia	Yes	Yes	ATC 5	Lowest	Biannually
Spain	Yes	Yes	ATC 5	Mean of 3 lowest	Biannually

Source: EMINET questionnaire completed by EEA-EFTA countries in June 2009

Appendix C: Consultation Process

Members of the group met with the following organisations in January and February 2010, most of which also made written submissions:

- Irish Pharmacy Union
- Hospital Pharmacists Association of Ireland
- Irish Medical Organisation
- Irish Hospital Consultants Association
- Irish College of General Practitioners
- An Bord Altranais
- Irish Pharmaceutical Healthcare Association
- Association of Pharmaceutical Manufacturers of Ireland
- Pharmaceutical Distributors Federation

Members of the group also met with representatives of patient and consumer advocacy groups in January 2010. An information session was also held in March 2010 for representatives of patient and consumer advocacy groups.

Key issues raised by stakeholders included:

- The need for a patient information campaign to promote awareness and understanding of interchangeable medicines and the proposed reference price system.
- The need for the HSE to consider supply issues when selecting reference groups and prices.
- The ability of prescribers to object to substitution of interchangeable medicines on medical grounds.
- Restricting substitution to medicines designated as interchangeable.
- Provision for the patient to opt for specific prescribed brands if they are willing to pay the additional cost, if any.

Further consultation on the draft legislation will occur as part of the formal regulatory impact assessment.

Appendix D: Draft Criteria for Interchangeability

Criteria for Interchangeability @ ATC Level 5

1. Only products licensed by the Irish Medicines Board (or the European Medicines Agency) can be determined to be interchangeable.
2. In general, generic drugs should be regarded as interchangeable with their reference product (see list of exceptions below)
3. Interchangeable products will contain the same amount(s) of the same active ingredient(s)
4. Different salts and esters of a chemical substance may be considered interchangeable
5. Interchangeable products will have the same route(s) of administration
6. Comparable tablet, capsule and other similar dosage forms of a chemical substance may be considered interchangeable
7. Colours of solid or liquid dosage forms or shapes will not affect interchangeability
8. In general, excipients will not affect interchangeability unless there is a particular reason for concern
9. Combination products may be considered interchangeable
10. Any other criteria deemed relevant by the CIM / HSE.

General circumstances where medicines will not be regarded as interchangeable (on the basis of current evidence and manufacturing standards) include the following:

1. Where there is a difference in bioavailability between brands of the same medicines, particularly if the medicine has a narrow therapeutic index. Changing preparations may result in sub-therapeutic or toxic doses.

Products in this group include the following:

- Antiepileptic medicines (e.g. Carbamazepine, Gabapentin, Lamotrigine, Phenytoin, Sodium Valproate)
- CFC-free Beclomethasone metered dose inhalers
- Ciclosporin
- Digoxin
- Lithium
- Tacrolimus
- Warfarin

2. Where modified release preparations are not interchangeable, particularly if the medicine has a narrow therapeutic index.

Products in this group include the following:

- Aminophylline modified release preparations
- Diltiazem modified release preparations
- Morphine oral modified release preparations
- Nifedipine modified release preparations
- Theophylline modified release preparations

3. Where there are important differences in formulation between brands of the same medicine.

Products in this group include the following:

- Botulinum toxin type A
- Buprenorphine patches
- Fentanyl patches
- Insulin
- Nicotine replacement therapy
- Morphine solid dose forms
- Oxycodone solid dose forms
- Tacrolimus - Prograf® and Advagraf® are not interchangeable
- Vaccines - determinations in relation to vaccines will be the responsibility of the National Immunisation Office

4. Where products contain multiple active ingredients.

Products in this group include the following:

- Antacids etc containing many ingredients
- Bowel cleansing solutions
- Calcium salts
- Hormone replacement therapy (oral & patches)
- Oral Contraceptives
- Oral rehydration salts
- Pancreatin supplements
- Saliva replacement products
- Skin and Scalp preparations

5. Where administration devices (e.g. inhaler or self-injection) have significantly different instructions for use and patient familiarity with the same product is important.

Products in this group include the following:

- Adrenaline (Epinephrine) pre-filled syringes
- Beclomethasone dry powder inhalers
- Formoterol dry powder inhalers

- Interferon alfa-2b pre-filled devices
- Interferon beta-1a pre-filled devices
- Salbutamol dry powder inhalers

6. Where the product is a biological rather than chemical entity. Generic versions of these medicines are known as biosimilars – they are not currently regarded as identical to the reference product.

Products in this group include the following:

- Erythropoietin
- Filgrastim

Appendix E: Communications Strategy

A draft communications strategy has been prepared and the key elements are outlined below. The draft communications strategy broadly identifies what public information initiatives would be required to support the introduction of this new system and makes an assessment of their costs.

Communications objectives

1. Make the public aware of the role of interchangeable medicines, their safety and efficacy.
2. Make patients and carers aware of the new reference pricing system and what will change for them when filling prescriptions.
3. Make GPs, Pharmacists, other health care workers, HSE staff, the voluntary sector and private nursing home sector aware of their role in the new system and how they can support patients when it is introduced
4. Assist public representatives, groups representing patients and service users and the media to fulfil their role as advocates for the public and provide accurate information on the new scheme

Costs

The overall cost of a comprehensive communications strategy is estimated at approximately €500,000. This would include the following:

- Printing of supportive professional information packs or tools for GPs, pharmacists and other health care workers;
- Television campaign;
- Radio campaign;
- Advertisements in national and regional Papers;
- Data entry and ongoing maintenance of HSE website tools, e.g. list of medicines covered, images of interchangeable medicines, etc.;
- Training and briefing of HSE Infoline staff;
- Information leaflets on the new scheme for distribution to GPs, pharmacies and HSE public offices and infoline.