

Pricing and Reimbursement of Medicines in Ireland – New IPHA/HSE Agreement.

The HSE has announced details of the new agreement with the Irish Pharmaceutical Healthcare Association (IPHA) on the pricing and supply of medicines for the Irish Health Service. The new agreement is for a period of 4 years and will come into effect on the 1st of September 2006. The agreement shall apply to all medicines granted a marketing authorisation by the Irish Medicines Board or European Commission, that can be prescribed and reimbursed under the Community Drugs Schemes and all medicines supplied to the HSE, state funded hospitals and to the state agencies whose functions normally include the provision of medicines. New medicines, including new presentations and applications, granted a marketing authorisation by the Irish Medicines Board or European Commission will become reimbursable under the schemes within 60 days of the date of the reimbursement application.

The HSE reserves the right to assess new and existing technologies (pharmaceuticals, diagnostics and devices) that may be high cost or have a significant budget impact on the Irish Healthcare system. Where a new medicine is subjected to pharmacoeconomic assessment the reimbursement decision will be notified within 90 days of the receipt of the reimbursement application. Assessments will be conducted in accordance with the existing agreed Irish Healthcare Technology Assessment guidelines. Products subjected to an assessment will become reimbursable under the schemes within 40 days of a positive reimbursement decision. Should reimbursement be refused an appeal may be made to an expert committee. The expert committee's decision will be made within a further 90 days and will be accepted as binding

The price to the wholesaler of each item of medicine covered by the new agreement will not be increased for the term of the agreement except under the provisions for price monitoring and review, price modulation or exceptional circumstances. The price to the wholesaler of any new medicine introduced to Ireland following the commencement of the agreement, shall not, on the date of initial price notification to the HSE exceed the currency adjusted average price to the wholesaler in the nominated EU member states which include, Belgium, Denmark, France, Germany, the Netherlands, Spain, the UK, Finland and Austria. If any new medicine is not available in all nominated EU states on the date of initial price notification to the HSE, the Irish price to the wholesaler shall not

exceed the currency adjusted average price to the wholesaler in the nominated EU states in which the new item of medicine is available. If a new medicine is not available in any of the nominated EU states, the Irish price to the wholesaler will be agreed between representatives of the manufacturer/importer concerned and HSE within 90 days of the date of the reimbursement application.

The price to the wholesaler of any new medicine introduced to Ireland under the new agreement shall be realigned to the currency adjusted average price to the wholesaler in the nominated EU member states in which the medicine is then available 2 years and 4 years following the commencement of the new agreement. Price changes (if any) resulting from these realignments would be implemented within 60 days of the realignment date. No realignment will be required within 12 months of the date of reimbursement approval. Price modulation will be permitted under the new agreement on an exceptional basis and on condition that any such product price modulation will be cost neutral for the state.

The agreement also includes the provision for price reductions on patent expired medicines under agreed conditions. The price reductions will apply to specific dosage forms of patent expired medicines where the identical pharmaceutical form of that medicine approved by the Irish Medicines board or EU commission is available for prescription under the Community Drugs Schemes and all medicines supplied to the HSE. For patent expired medicines, the price to the wholesaler will be reduced by 20% and a further 15% of the original price 22 months after the first price reduction.

The HSE will notify the manufacturer/importer of the availability of identical pharmaceutical form from another manufacturer and the new discounted price applicable. The rebate to the HSE for medicines dispensed under the GMS scheme will be 3.53% however no GMS rebate will be payable on the specific dosage forms of medicines which are subject to the price reduction outlined above. A single price across the hospital and community supply is also a feature of the new agreement. Further details in relation to the new agreement may be obtained at www.hse.ie.

