

## Research papers

# The use of patient group directions for Zanamivir in 2000/2001: cross-sectional survey of primary care organisations in England

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### ABSTRACT

**Background** In November 2000, the National Institute for Clinical Excellence (NICE) issued guidance on the use of Zanamivir for high-risk patients with influenza. The Department of Health introduced patient group directions in August 2000 in order to allow primary care organisations to permit nurses and pharmacists to supply certain medications, such as emergency contraception, under defined circumstances without a general practitioner (GP) prescription.

**Aims** To report on the implementation of patient group directions for Zanamivir, in particular their utilisation, feasibility and acceptability, and to derive recommendations for the future use of patient group directions.

**Design** Cross-sectional postal questionnaire survey  
**Setting** All 474 primary care organisations in England in March 2001

**Participants** Clinical governance leads

**Outcomes** Whether a patient group direction was

used or not and the reasons why; the timing of the implementation; the utilisation of patient group directions by pharmacies, practices and patients; the proportion of patients referred to their GP; the number of adverse events recorded; the cost of setting up and running patient group directions and any specific issues which arose.

**Results** The response rate was 338/474 (71.3%). Forty-three (12.7% of 338 respondents) reported that their organisation used a patient group direction for Zanamivir. The main reasons for not using a patient group direction for Zanamivir were: time or other resource constraints; concerns over validity and appropriateness of the NICE guidance for Zanamivir; concerns regarding the cost-effectiveness of Zanamivir, and its appropriateness for a patient group direction approach. Other reasons included competing priorities with other initiatives such as flu immunisation; concerns about the appropriateness or safety of patient

group directions for a new black triangle drug; lack of clinical need or demand; an absence of the necessary decision-making processes; lack of agreement between stakeholders; the use of a reasonable alternative; other practical implementation difficulties including inadequate training.

**Conclusions** The Department of Health's response to the workload implications of the introduction of Zanamivir was to introduce patient group direc-

tions. However they need to be in place before an epidemic and were not significantly in place for the winter of 2000/2001. In the event of a flu epidemic this winter, on this evidence, primary care is unlikely to cope with a high demand for fast access to Zanamivir.

**Keywords:** influenza, nurses, patient group directions, pharmacists, prescribing

## Introduction

The National Institute for Clinical Excellence (NICE) was set up as a special health authority for England and Wales in 1999. It has three main functions: to appraise new technologies, to produce or approve guidelines and to encourage improvement in quality.<sup>1</sup> On 9 October 1999, NICE undertook its first appraisal. It conducted a fast track appraisal of the anti-flu drug Zanamivir (Relenza), which reduces flu symptoms, on average, from 6 to 5 days. It advised health professionals not to prescribe Zanamivir for the treatment of flu during the winter of 1999/2000. This was because of a lack of evidence of its effectiveness in high-risk individuals and uncertainty about cost.<sup>2</sup> At the same time NICE also advised that flu immunisation remained the most effective intervention in preventing complications. It reviewed its decision following new evidence that Zanamivir reduces the absolute risk of complications in which antibiotics are needed by 6%.<sup>3</sup> On 21 November 2001, NICE issued guidance stating that 'Zanamivir should be used to treat "at risk" individuals when influenza is circulating in the community and if they present within 36 hours of developing symptoms'.<sup>4</sup>

While the profession welcomed the availability of Zanamivir, with its potential to ameliorate flu symptoms and potentially reduce serious complications, there were still concerns regarding (a) the degree of likely benefit, (b) the practicalities of implementing such complex advice, and (c) the implications of this NICE guidance for increasing general practitioner (GP) workload.<sup>2,5,6</sup>

The Department of Health introduced patient group directions in August 2000 in order to allow primary care organisations to permit nurses and pharmacists to supply certain medications under defined circumstances without a GP prescription.<sup>7</sup> In the light of the NICE guidance on Zanamivir, the Department of Health issued an example patient group direction in November 2000 (see Appendix 1).<sup>8</sup> This specified criteria for the use of Zanamivir, criteria for seeking further advice, adverse reactions

and the information to be recorded in the patients' records (dose, frequency, quantity of Zanamivir supplied, date, batch number, expiry date and identity of person issuing the prescription). By law, patient group directions need to be signed by a doctor, a pharmacist and by the appropriate health organisation.<sup>7</sup>

As it turned out, there were few cases of influenza in the winter of 2000/2001 and no epidemic therefore there was no need for a patient group direction for Zanamivir. However, for future implementation, considerable planning and training is needed for a patient group direction to be in place at the onset of an epidemic. Therefore an examination of patient group directions for Zanamivir can be used to look at both the introduction of a new initiative to expand medication availability and also at one potentially useful mechanism for coping with additional workload during a flu epidemic.

The aim of this study is to report on the implementation of patient group directions for Zanamivir, in particular their utilisation, feasibility and acceptability and to derive recommendations for their future use. Patient group directions for this drug and others are likely to assume great importance for primary care.

## Methods

### Study population and questionnaire

We conducted a cross-sectional postal questionnaire survey of all clinical governance leads in all the primary care organisations (primary care groups [PCGs] or trusts) in England that were in existence in March 2001. Primary care organisations in Wales were excluded as patient group directions were not legal there during 2000/2001. The questionnaire determined whether or not patient group directions had been used and the reasons why; the timing of the implementation; the utilisation of patient group

directions by pharmacies, practices and patients; the proportion of patients referred to their GP; the number of adverse events recorded; the cost of setting up and running patient group directions and any specific issues which arose. Reminders, which were sent after three weeks, consisted of an abbreviated questionnaire enquiring whether patient group directions had been used or not and the reasons for the answer. An abbreviated questionnaire was used to maximise response rates at a time of considerable health service reorganisation. Ethical approval was obtained from the Multi-Centre Research Ethics Committee in Trent.

## Characteristics of primary care organisations

We constructed a database of characteristics of primary care organisations using the National Primary Care Research and Development site. It contained the following variables, each of which has been considered relevant to process and outcome measures:<sup>9</sup> the mean list size per whole-time equivalent GP; the proportion of practices that are single-handed; the proportion of GPs who are female; the proportion of GPs who are approved trainers; the Townsend score and Under Privileged Area (8) score.<sup>10,11</sup> We also included the proportion of patients aged 65 or over as these patients were considered to be at high risk of complications of influenza. These data were used to compare the characteristics of respondents and non-respondents to our questionnaire and also to compare characteristics of primary care organisations that used a patient group direction during the winter of 2000/2001 with those who did not.

## Analysis

Comparisons of characteristics of primary care organisations that did and did not use patient group directions were made using Mann–Whitney *U* tests. Summary statistics (percentages, means, medians) were calculated as appropriate.

The free text answers from each respondent to the question ‘Why did you not use a patient group direction?’ were imported into a qualitative analysis programme (QSR N5) so that a content analysis could be undertaken. A coding frame was developed by examining each individual response. This was systematically applied and the completeness of the coding was checked by searching on keywords in the text. A second researcher coded 50 responses independently to help improve the reliability of the analyses.<sup>12,13</sup> The inter-rater reliability was very good with a median kappa of 0.89 (range 0.66 to 1.00)

across 16 nodes used for coding. The coding table was exported to SPSS (version 10.07) with one case representing each respondent.

## Results

### Study population

In total there were 474 primary care organisations in existence in March 2001. We received a total of 338 responses (71.3% of 474). The characteristics of the 338 primary care organisations from which we obtained a response were very similar to the 136 remaining organisations (results not presented due to lack of space).

The characteristics of the 43 primary care organisations that used a patient group direction were compared with those that either did not use one, or did not know (see Table 1). The two groups were similar for all variables except that those that used a patient group direction had a marginally higher proportion of subjects aged 65 years and over.

Of the 338 respondents, 224 (66.3%) were GPs, 36 (10.7%) were nurses, 27 (8.0%) were pharmacists, 21 (6.2%) were prescribing advisors, 12 (3.6%) were public health consultants, one was a practice manager, and 17 (5.0%) did not specify their discipline. Twenty-three respondents (two GPs, 11 prescribing advisors, 10 pharmacists) completed the questionnaire on behalf of the clinical governance lead.

### Utilisation of patient group directions

Of the 43 respondents who reported use of a patient group direction, 23 (54%) completed the unabbreviated questionnaire. Five respondents reported that one patient had received Zanamivir through a patient group direction; 12 reported that no patients had received Zanamivir and six did not know. No adverse events were reported by the five respondents who had issued Zanamivir through a patient group direction.

When asked whether they would use patient group directions for Zanamivir again next winter, seven (30% of 23) said no, 12 (52% of 23) said yes and three (13%) said they didn’t know. Twenty-one (91% of 23) reported they would use patient group directions again for other therapies.

### Reasons for using patient group directions for Zanamivir

Of the 43 respondents who used a patient group direction for the administration of Zanamivir, 19

**Table 1** Characteristics of primary care organisations that did and did not use a patient group direction

	Used patient group direction ( <i>n</i> = 43)			Did not use patient group direction ( <i>n</i> = 295)			<i>P</i> value
	Median	25th percentile	75th percentile	Median	25th percentile	75th percentile	
Number of practices per organisation	17.0	14.0	26.0	18.0	13.0	24.0	0.51
Whole-time equivalent GPs	55.0	45.0	81.0	54.0	42.5	71.0	0.56
Percentage of GPs that are female	30.8	22.2	37.8	31.4	25.8	37.9	0.37
Percentage of practices that are single-handed	27.5	14.8	38.1	23.1	11.1	37.5	0.44
Percentage of GPs that are dispensing	7.7	0.0	23.1	4.9	0.0	27.1	0.72
Townsend score for primary care organisation	-0.7	-2.7	1.4	-1.3	-2.6	1.2	0.89
Percentage of GP principles that are trainers	11.4	7.4	14.5	12.2	7.1	16.7	0.33
Mean list size per whole-time equivalent GP	1898.2	1752.5	1995.6	1877.1	1733.0	2017.1	0.88
Percentage of patients aged 65 or over	16.5	15.1	18.5	15.8	13.8	17.0	0.01

gave reasons for doing so. The reasons for choosing to use a patient group direction and number of times cited (in brackets) were:

- to relieve pressure on GP time or allow others to prescribe Zanamivir (15)
- it was requested or implemented at a higher level, e.g. the health authority (5)
- simply following Department of Health guidelines or recommendations of NICE (1)
- it was decided that it was necessary to support healthcare professionals to give Zanamivir (2)
- to prevent hospital admissions due to flu complications (1)
- to test the water with GP acceptance of patient group directions (1)
- to improve access for patients (1).

Of the 295 respondents who did not use a patient group direction, 22 (7.5%) implemented an alternative solution such as disseminating NICE guidelines to their practices.

### Reasons for not using patient group directions for Zanamivir

Two-hundred-and-ninety-one primary care organisations reported that they did not use a patient group direction for Zanamivir in the winter of 2000/2001 and four did not know if they used one for Zanamivir. Two-hundred-and-eighty-five respondents (96.6% of 295) gave reasons why patient group directions had not been used. The responses fell into two broad categories – implicit or explicit concerns about NICE guidance for Zanamivir (60 respondents had one or more concerns), or issues relating specifically to the principles and application of patient group directions (200 respondents had one or more concerns). The remaining respondents had not considered it, did not know the reasons, had alternative arrangements or had plans to develop patient group directions in the future. In many instances, respondents gave more than one reason:

#### *Lack of time*

Ninety respondents (31% of 295) mentioned lack of time as a reason for not implementing patient group directions. The NICE announcement was in late

November which was only weeks before the expected onset of the flu season. Respondents said there was inadequate time to get consensus, draw up documents, undertake training and implement within the necessary timescale safely.

### ***Concerns about the NICE guidelines for Zanamivir***

Twenty-five respondents (9% of 295) specified concerns regarding the appropriateness, feasibility and validity of NICE guidance (see Box 1). Some expressed concerns that the NICE guidance had been politically or commercially motivated or that the NICE guidelines did not reflect the current evidence or were flawed. Some verbatim quotes can be found in Box 1.

### ***Concerns about the effectiveness of Zanamivir***

An additional 35 respondents (12% of 295) were concerned about the quality of the evidence for the effectiveness of Zanamivir although NICE was not specifically mentioned. Some thought the evidence was questionable or they agreed with alternative recommendations made by the Drugs and Therapeutics Bulletin. Others believed the stated clinical benefit but considered this was too small to justify its use. An additional four respondents were concerned

about the safety or possible side-effects of the new drug for patients.

### ***Concerns about the appropriateness of a patient group direction for Zanamivir***

There were 35 respondents who said the use of patient group directions for Zanamivir was inappropriate. The reasons given were: only doctors should prescribe a black triangle drug (i.e. a drug recently licensed and subject to special reporting arrangements for adverse reactions) in its first year; the guidance from NICE had been controversial making it less suitable for patient group directions; influenza does not lend itself to patient group directions due to the clinical uncertainty of diagnosis and the need to deal with high-risk patients directly; nurses and pharmacists were not in a position, or had not been trained, to make a differential diagnosis of flu; difficulties in assessing whether patients need antibiotics (see Box 2).

### ***Concerns about drug cost, availability or resulting workload***

Nine respondents (3% of 295) specifically mentioned concerns about the cost of prescribing Zanamivir. Four respondents were concerned about the availability or supply of the drug. Two respondents reported that they did not wish to encourage the

#### **Box 1 Quotes on effectiveness of Zanamivir and NICE guidelines**

‘The NICE guidance was insufficiently robust to give us confidence in Zanamivir’s benefit – e.g. its original guidance on Zanamivir was reversed after appeal by manufacturer.’

‘Uncertain about clinical and cost effectiveness of Zanamivir – all practices felt NICE were under commercial pressure re Zanamivir and guidelines were flawed.’

‘Did not want to do anything to encourage the uptake of a relatively ineffective drug.’

‘The reduction of length of illness from 6 to 5 days is not a compelling indication for a new drug.’

‘Load of rubbish i.e. D&T Bulletin disputing NICE recommendation.’

‘Did not agree with the NICE guidance which was in my honest opinion APPALLING.’

‘It was rubbish and lost NICE considerable credibility.’

‘... the complexity of knowing when Zanamivir was prescribable and when not. Flu needed to be in the community above a certain level before Zanamivir was prescribable – how was this information disseminated? – certainly not to PCGs so how could we advise community pharmacists of the current position?’

‘We were too busy to take the NICE Zanamivir guidelines seriously.’

‘There has recently been some work on GPs’ perception of NICE guidance on Relenza – it is not particularly favourable with up to 70% of GPs ignoring its findings and questioning the credibility of the advice and the organisation.’

### **Box 2** View from respondents about the use of patient group directions

‘The health authority could not decide which pharmacist should sign it!’

‘Discussions between HA [health authority] and LMC [local medical committee] felt that pharmacists would be unable to diagnose true influenza or distinguish from other respiratory infections. The use of testing steps was given no credence. The subject of pharmacist liability and lack of training was also a concern.’

‘The health authority couldn’t be bothered.’

‘Our health authority advice was that no patient group direction should be implemented. As they need to be signatory to any patient group direction put into place there was no point in producing one.’

‘Not sure. Presumably everyone was too busy to write one. Not discussed at either clinical committee or prescribing sub-committees of PCG.’

‘Although we have good experience of patient group directions we did not feel they were appropriate for the use of a new and unproven medication that most doctors would hesitate to use.’

‘We considered patient group direction at our clinical governance support team but with the fast changing NHS it was another change we could not put into practice with (1) lack of staff on PCG; (2) lack of time for doctors; (3) lack of time for staff; (4) no resources allocated; (5) not being included in our HIMP [Health Improvement and Modernisation Programme].’

‘We had grave concerns regarding the standard of patient group direction and supporting education of pharmacists we would be able to put together and implement in the run-up to Christmas. In the event very few prescriptions were issued for the country as a whole.’

‘We are currently debating the use of patient group directions within our PCG. Feel their use is as clear as mud!’

‘GPs felt the very patients requesting the drug were the ones they wanted to be seeing.’

‘Did not think there would be enough time to train community pharmacists and nurses in giving Zanamivir under a patient group direction.’

‘Not a priority action. Concentrate on immunisation policy.’

use of Zanamivir because of fears that it may generate an increased workload.

#### ***General comments around patient group directions***

Three respondents stated that the issue was not considered or never arose. Seven organisations did not use patient group directions for Zanamivir although they were using patient group directions for other initiatives such as childhood immunisations, emergency contraception, travel vaccines and influenza immunisation. Twenty-four (8% of 295) respondents indicated that patient group directions were under consideration or development for implementation later although some did not understand the guidance.

#### ***Concerns about the safety of patient group directions***

Seven respondents (2%) were concerned specifically about the safety of patient group directions, particularly with the lack of time to undertake satisfactory

training. One respondent stated that ‘clinical and legal risk was too great with no clear line of accountability for the patient group direction over the whole PCG’.

#### ***Difficulties in implementing patient group directions***

Forty respondents (14% of 295) said they had not used patient group directions for Zanamivir because of issues relating to obtaining agreement and backing of the appropriate professionals or organisations. Nineteen respondents (6% of 295) had concerns about the practical implementation of patient group directions (rather than its appropriateness). The difficulties mentioned included lack of capacity and infrastructure to implement a patient group direction; difficulties in agreeing fees and mechanisms for paying pharmacists; concerns over organising appropriate training for all necessary staff; cumbersome and complex guidelines; lack of management resources to draw up, approve and implement a patient group direction; and the need for a separate budget

agreement, duplicate forms, and an audit trail. Twenty-five respondents (9% of 295) remarked that they had inadequate resources (in addition to lack of time) to implement the patient group direction (see Box 3). The main items mentioned included resources for training and pharmacist fees.

## Discussion

This is the first report of the utilisation and acceptability of patient group directions within the National Health Service. The whole concept of patient group directions is new and of tremendous potential importance for primary care. There are public health implications that could benefit communities greatly. How these directions are implemented is therefore important in terms of their successes and failures.

We took the first opportunity possible to explore the use of patient group directions which resulted in an exploration of the implementation of directions for NICE guidelines for Zanamivir. As it turned out there was no flu epidemic in the winter of 2000/2001. However if patient group directions are to be implemented to ease workload and capacity problems, they must be in place before an epidemic starts.

We achieved a good response rate although the questionnaire was administered in March 2001, a time of considerable reorganisation within the NHS. The non-responders were from primary care organisations with similar characteristics to the responders, suggesting that our sample is unlikely to be biased and our results are therefore likely to be generalisable.

Where patient group directions were in place, their use was minimal which is expected given the absence of a flu epidemic. Over 90% of those who used a patient group direction would use one again for other therapies although only half would do so for Zanamivir. The vast majority of organisations did not implement a patient group direction for Zanamivir and most of these gave their reasons. Not only were the respondents from primary care organisations uncertain about the validity of the NICE guidelines and the effectiveness of Zanamivir, but there were also concerns about the appropriateness of using a patient group direction to deliver treatment with a black triangle drug. The Department of Health states that black triangle drugs may be included in patient group directions provided such use is exceptional, justified by current best clinical practice (e.g. NICE guidance) and that a direction clearly describes the status of the product.<sup>7</sup> Time constraints were also a major factor for not using a patient group direction for Zanamivir.

A minority of primary care organisations had used patient group directions for other purposes or had one under development which suggests that they did not disagree with the principle of patient group directions. Other organisations did not consider patient group directions to be appropriate or safe in this context. Other reasons given for not using patient group directions were competing priorities; insufficient clinical need or demand; lack of agreement between stakeholders; use of reasonable alternatives; implementation difficulties and inadequate resources or training.

### Box 3 Further views on resources for patient group directions

‘My estimated cost of preparing a patient group direction would be estimated as follows:

- preparation of the patient group direction, drafting and finalising: £1500
- dissemination to practices and community pharmacists: £32
- reimbursement for pharmacist/nurse time: £5 per intervention assuming a 25% uptake of drug in ‘at risk’ population maximum figure £8381
- drug cost based on the above could be £36 425
- total overall cost (estimated) £46 6626.

This does not allow for complications or adverse drug reactions of Relenza use.’

‘Who pays pharmacists for patient group directions’ added work?’

‘Pharmacists not necessarily cost-effective way of providing service.’

‘Drug budgets had been already allocated to GP practices – there was no other source of funding available other than somehow allocating the prescribing back to the practices, which would be a very complex task and how would the PPA [Prescription Pricing Authority] get prescribing data?’

## Recommendations for the future use of patient group directions

One of our aims was to derive recommendations to help guide the future use of patient group directions. In order for patient group directions to be implemented successfully, the following elements are required:

- an actual or perceived need relating to clinical care, GP workload or patient access to services in order to justify the additional resources needed to devise and implement the patient group direction rather than continue with current practice
- an indication that can be readily recognised by non-doctor healthcare professionals: the recognition of flu can be difficult
- the availability of a proven and cost-effective treatment (preferably one which is not black triangle status) associated with clear guidelines. This needs the backing of GPs who would otherwise provide the care and public health consultants who would approve treatments, as well as the healthcare professionals who would deliver the patient group direction
- clear guidance on the implementation of the patient group direction for primary care organisations including advice on its legal status and the authorisation process
- prior training and education for all clinical and administrative staff likely to be involved in implementation
- adequate resources (including both funding and time) to implement the patient group direction effectively, safely and within the necessary time-scale. There need to be clear mechanisms for reimbursement of pharmacy and other staff in addition to funding the direct treatment costs.

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## Appendix 1

Example of a patient group direction for Zanamivir produced by the Department of Health

Patient group direction comes into effect: Date:	
Patient group direction [Review][Expiry]: Date:	
Medicine name	Zanamivir (Relenza)
Professionals to which applies:	Pharmacists, registered nurses
Lead doctor's signature:	
Lead pharmacist's signature:	
Lead nurse's signature (where appropriate)	
On behalf of [health organisation] signature:	
<b>Clinical condition</b>	Influenza is characterised in its early stages by sudden onset of pyrexia associated with aches and pains, anorexia. Sore throat, nausea, vomiting and a harsh unproductive cough are common.
Criteria for inclusion:	<p>Influenza isolates and RCGP tracking shows flu consultations &gt; 50/100 000 per week: at-risk individuals (aged <math>\geq</math> 12 years) fitting one or more of these categories:</p> <ul style="list-style-type: none"> <li>• age 65 years or over</li> <li>• chronic respiratory disease (including chronic obstructive pulmonary disease [COPD] and asthma) requiring regular medication</li> <li>• significant cardiovascular disease (excluding uncomplicated hypertension)</li> <li>• immunosuppressed (due to treatment or illness such as asplenia or splenic dysfunction)</li> <li>• diabetes mellitus</li> <li>• presenting within 36 hours of onset of symptoms with most of the following: <ul style="list-style-type: none"> <li>– rapid onset (hours) from feeling well to very ill</li> <li>– prostrating malaise</li> <li>– profound myalgia</li> <li>– marked fever/feverishness (<math>\geq</math> 37.8°C oral)</li> <li>– headache – early and may be severe</li> <li>– only minimal nasal secretions</li> <li>– appetite limited or absent.</li> </ul> </li> </ul> <p>Cough and sore throat may also be present but also commonly occur in other URTIs [upper respiratory tract infections]. Nausea and vomiting may also be present.</p>

Seek further advice for: [Fill in arrangements for obtaining advice]	Rash Breathing difficulty Disturbance of consciousness Pregnancy Breastfeeding Other significant symptoms not mentioned under 'clinical condition'.
<b>Description of treatment</b>	
Name of medicine:	Zanamivir (zanamivir)
*POM/P/GSL:	POM
Form:	Powder in blister
Strength:	5 mg
Dosage:	Contents of two blisters (2 × 5 mg) inhaled twice daily by Diskhaler
Total daily dose	20 mg
Duration of treatment	5 days
Total treatment quantity	100 mg
Follow-up:	None
Adverse reactions: rare	Oropharyngeal oedema, bronchospasm, dyspnoea, throat tightening or constriction, rash
Written and verbal advice for patient/carer:	Demonstrate loading Diskhaler, advise on inhalation technique and ensure patient understands dosing regime. Advise patient to read the patient information leaflet. Warn that if patient's condition deteriorates, e.g. increasing fever or temperature does not settle after 4–5 days, or if patient experiences breathing difficulties or chest pain, or an underlying condition worsens, a doctor should be contacted. Warn patient with asthma or COPD of bronchospasm risk and need for fast-acting bronchodilator to be on hand. If adverse reaction develops, patient to stop treatment with Zanamivir immediately and contact doctor.
Records of supply/administration for audit:	Following to be noted in the patient's records: <ul style="list-style-type: none"> <li>• dose, frequency and the quantity of Zanamivir supplied</li> <li>• date of supply to patient</li> <li>• batch number and expiry date</li> <li>• signature of person supplying Zanamivir.</li> </ul>

\*POM: prescription-only medicine; P: pharmacist; GSL: general sales list