An ageing population is placing high demands on healthcare but national measures to try to improve efficiency and save on cost do not always tally with regional initiatives – adding to the challenges in this market.

ITALY AT A GLANCE

**FOCUS ON**

**AREA:** 301,230 sq km

**POPULATION:** 58.1 million

**LIFE EXPECTANCY:** 78 years (men), 84 years (women)

**GNI PER CAPITA:** $28,840 (WHO, 2005)

**TOTAL EXPENDITURE ON HEALTH PER CAPITA:** $2,414 (WHO, 2005)

**TOTAL EXPENDITURE ON HEALTH AS % OF GDP:** 8.7 (WHO, 2005)
in the short term but have showed little long-term vision.

improving the situation.

seems to have increased inefficiencies in the system rather than

organisation of healthcare was devolved to the regions but this

strain on resources.

the provision of retirement pensions in particular is placing a

because of a reluctance to pay for them.

restrictions in introducing innovative and more expensive drugs

included. Pharma companies have met with difficulties and

expenditure – 12.2 per cent in 2006 – or a more significant 16 per

pay-back to the reduction of prices. Some of these have worked

to cut back on expenses – 18 in fact during the past five years – from

Nazionale

would present an opportunity for the pharmaceutical sector if it

demands on healthcare both economically and politically. This

The Italian population is the oldest in the EU making high

Premium price for

Fast track and

terms and less than 7 per cent of total volume of drugs.

estimates that the generics market to be worth €1.76bn by the end

18.4% of 2007, representing just 4 per cent of the whole market in monetary

"Public spending on healthcare is

one of many increasing welfare

and innovations

costing"

in the sector of the pharma market dealing

This has had an effect on the sector of the pharma market dealing

In November 1998, the responsibility for management and

the end of the war in 1945. The king, Victor

he was killed by partisan Italians at the

Benito Mussolini gaining power in 1922.

political climate. Three years after fighting

opera but also for its sometimes volatile

Italy is famous for its art, architecture and

INTRODUCTION

The association of generic drugs producers in Italy (Assogenerici

The Italian people are not very satisfied with the government, which is

the armed forces and has powers to veto

Italy was one of the six countries to sign

the European Union (EU) in 1957. The

one of many increasing welfare

Public spending on healthcare is

one of many increasing welfare

and innovations

costing"
One of the most important changes in the Italian administrative system is the devolution to the regions of much of the healthcare decision making. This has had a significant impact on the regulation of scientific information (see table below), the control of pharmaceutical expenditure and the access to hospital markets. The resulting some contradiction and incongruence importantly is having a massive effect on pharma’s strategic approach to the market. There are now several regional markets within Italy with real differences in regulation. Pharma is still adjusting to this change and those who understand and can meet the needs of these new markets will gain a competitive advantage. Static, repetitive, marketing will need to give way to a more dynamic, modern approach that responds quickly to change.

**THE PPIS-LIGURIA CASE**

Devolution of the system has sometimes resulted in a misalignment between the Italian medicines agency’s (AIFA) national strategies on pharmaceutical expenditure and the opinions of the now autonomous regional leaders.

In December 2006, **Regione Liguria** (followed by other regions) decreed that doctors must prescribe the lowest-priced generic proton pump inhibitor (PPI), lansoprazol, for at least the initial four weeks of therapy. This means patients must pay the difference in price between lansoprazol and any other prescribed drug in the class. This goes against the AIFA which recommends refunds for a range of PPIs. Court action followed resulting in media coverage about ‘the state’s drug’. The case looks set to go in the pharmaceutical companies’ favour, but the case has been adjourned until October while the court deliberates the constitutionality of the **Regione Liguria**’s decree.

Little has been done in Italy either on a national or regional level to encourage healthcare professionals to explain or promote the use of generic alternatives to their patients.

**NEW MARKET CHALLENGES**

**ITALY**

<table>
<thead>
<tr>
<th>Regions</th>
<th>Mandatory access modalities</th>
<th>Max no of visits per product</th>
<th>Promotional initiative limitations SSR reporting</th>
<th>ASL/AO (Decree date)</th>
<th>Doctors invited to congresses</th>
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TABLE 1: REGIONAL REGULATION OF SCIENTIFIC INFORMATION 2003–2007

FIGURE 4: PUBLIC HEALTH SPENDING VERSUS INFLATION

<table>
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<th>reimbursable medicines</th>
<th>total medicines</th>
<th>inflation</th>
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<td>2001</td>
<td>115</td>
<td>105</td>
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<td>2006</td>
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MEETING THE FUTURE

Prime Minister, Romano Prodi, Health Minister, Livia Turco, and Minister of Economic Development, Pier Luigi Bersani, attended the Asssemblea Publica di Farmindustria in June 2007. This meeting was held in an attempt to stabilise the country's healthcare system. Up for discussion were medium-term plans and programmes, the introduction of rewards for innovation, fast-track reimbursement and price alignment with other established EU Member States. These initiatives should guarantee patients better access to innovative drugs and also promote growth and investment in the industry. They also require more efficient management of funds from payers on a national and regional level. In some regions, patients may wait over a year to have their payments reimbursed. There also remains a general economic imbalance between the north and south of the country.

One positive healthcare initiative taken at national level is the plan to offer free vaccinations against human papillomavirus (HPV) to all girls at 12 years old.

ITALY

FOCUS ON

In August 2006, the Italian over-the-counter (OTC) market faced a major turning point as the system was opened up in an attempt to break the pharmacists' monopoly. Retail outlets can now sell OTC drugs but only if a pharmacist is available on the premises for customers to consult if they need to.

For supermarkets and large stores this restriction will involve some organisation, along the lines of having designated areas managed by a pharmacist during opening hours. The revenue created would have to be sufficient to cover all costs and salaries.

Italy does not make a distinction between general sales list drugs and pharmacy-only drugs as happens in the UK. ‘Parapharmacies’ are also becoming more common; these are pharmacist-led selling points dedicated to wellbeing and offering OTC drugs with other healthcare products. These changes followed a lively debate with one side viewing it as an opportunity for development and better service while the other side feared it would lead to consumers adopting an unguarded attitude towards their healthcare.

The latter's concern was that making drugs more freely available would encourage people to take more medication than they actually needed. In July 2006, market data research conducted by Censis on behalf of national association for the self-medication pharmaceutical industry (ANIFA) was presented at the Osservatorio sull'Automedicazione. It showed that the Italian OTC market in 2006 had decreased in value (-7 per cent) and volume (-4 per cent) and that Italian consumers do have a responsible attitude toward OTC drugs.

THE ECONOMICAL DATA

Values have decreased because of the elimination of the nationwide pricing system in 2006, which gave retailers freedom to reduce prices on certain items. Explaining why the volume of drugs sold has also decreased, in spite of increased distribution, is more complicated. Research by Censis indicates that Italians buy drugs only when they need them and the reason for the drop in volume has been attributed to ‘seasonal’ effects on the OTC market.

THE OTC MARKET

NEW MARKET CHALLENGES CONTINUED

Maurizio Mioli is managing director and CEO at Sudler & Henessey, Italy
A rise in the self-medication market in Italy has contributed to the mild winter of 2006, which lowered the rate of influenza infection resulting in decreased sales.

A president of the Senate’s Commission for Health, Danilo Toninato, pointed out that the new regulations are designed to improve the OTC sector, which is considered to be underdeveloped in Italy. This is a specific area of focus for the OTC sector in Europe, where there is a desire to launch new products that capitalize on established brands.

The OTC sector is a key area of focus in Italy due to the government’s push for...