

Societal Impact of Pain
Brussels 3-4 May 2011

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Analgesics for the treatment of pain in Italy

AGENZIA ITALIANA DEL FARMACO

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Legislation milestones of pain therapy in Italy (1)

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- Law 39/**1999**: established citizens' right to access palliative care and set up a programme for the creation of hospices in each Italian Region.
- Law 12/**2001**: aimed at a more effective treatment of pain in end-of-life care and in patients with serious chronic pain; home delivery of opioid analgesics.
- DM 4 April **2003**: simplified medical prescription of opioid analgesics including combinations (e.g. atropine + morphine; codeine + paracetamol);
- Law 49/**2006**: distinction between potentially abusive substances and the related medicinal products.

Legislation milestones of pain therapy in Italy (2)

- DM 18 April **2007**: extended the use of opioid analgesics to serious pain of various nature (e.g. in tumours, surgery, bone fractures etc.).
- Law 38/**2010**: further simplification of access to medications for treatment of pain and palliative care; inclusion of pain levels into patients case history; education of health care professionals; use of a simplified prescription form.

The old three-part opioid prescription form

<p>PER IL MEDICO</p> <p style="text-align: right;">N° K 0865832</p> <p style="text-align: center;"></p> <p>Ammalato _____ <small>(Cognome e nome)</small></p> <p>Residenza _____</p> <p>Prescrizione _____ <small>(In tutte lettere)</small></p> <p>Dose, modo e tempi di somministrazione _____ <small>(In tutte lettere)</small></p> <p>_____</p> <p>Data di prescrizione _____</p> <p>Firma del medico _____ <small>(Da apporre all'atto della prescrizione)</small></p> <p>Domicilio del medico _____</p> <p style="text-align: right;">Tel. _____</p> <p>Timbro del medico _____</p> <p>COPIA PER DOCUMENTAZIONE</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">ENTE MUTUALISTICO</td> <td style="width: 50%;">NUMERO LIBRETTO</td> </tr> </table> <p style="text-align: right;">N° K 0865832</p> <p>Ammalato _____ <small>(Cognome e nome)</small></p> <p>Residenza _____</p> <p>Prescrizione _____ <small>(In tutte lettere)</small></p> <p>Dose, modo e tempi di somministrazione _____ <small>(In tutte lettere)</small></p> <p>_____</p> <p>Data di prescrizione _____</p> <p>Firma del medico _____ <small>(Da apporre all'atto della prescrizione)</small></p> <p>Domicilio del medico _____</p> <p style="text-align: right;">Tel. _____</p> <p>Timbro del medico _____</p> <p style="text-align: right;">Data di spedizione _____</p> <p style="text-align: center;">COPIA PER L'ENTE MUTUALISTICO</p> <p style="text-align: right;"><small>TIMBRO DELLA FARMACIA</small></p>	ENTE MUTUALISTICO	NUMERO LIBRETTO	<p>PER IL FARMACISTA</p> <p style="text-align: right;">N° K 0865832</p> <p style="text-align: center;"></p> <p style="text-align: center;"></p> <p style="text-align: center;">Ricetta per la prescrizione e la spedizione di stupefacenti e sostanze psicotrope (Legge n. 685 del 22-12-1975).</p> <p>Ammalato _____ <small>(Cognome e nome)</small></p> <p>Residenza _____</p> <p>Prescrizione _____ <small>(In tutte lettere)</small></p> <p>Dose, modo e tempi di somministrazione _____ <small>(In tutte lettere)</small></p> <p>_____</p> <p>Data di prescrizione _____</p> <p>Firma del medico _____ <small>(Da apporre all'atto della prescrizione)</small></p> <p>Domicilio del medico _____</p> <p style="text-align: right;">Tel. _____</p> <p>Timbro del medico _____</p> <p>Firma del medico _____ <small>(Da apporre 20 anni dal ritiro della prescrizione)</small></p> <p style="text-align: right;"><small>CURA DEL FARMACISTA</small></p> <p>Acquirente _____</p> <p>Documento di riconoscimento _____ N. _____</p> <p>Rilasciato da _____</p> <p>Data di spedizione _____</p>
ENTE MUTUALISTICO	NUMERO LIBRETTO		

The new simplified prescription form



AGENZIA ITALIANA DEL FARMACO

SERVIZIO SANITARIO NAZIONALE REGIONE

C 492422

ASSISTITO (o proprietario dell'animale) _____

INDIRIZZO _____

PREZZO: _____

ACQUIRENTE
 Carta d'identità
 Patente
 Passaporto
 Altro

N° documento _____
Rilasciato da _____

1° prescrizione

N° confezioni in lettere _____
Posologia (nel modo e nel tempo in lettere) _____

2° prescrizione

N° confezioni in lettere _____
Posologia (nel modo e nel tempo in lettere) _____

CODICE NUMERO CODICE NUMERO CODICE NUMERO
CODICE NUMERO CODICE NUMERO CODICE NUMERO

Ricetta Legge n° 12 del 8 febbraio 2001

TIMBRO MEDICO, INDIRIZZO E N° TELEFONO PROFESSIONALE

FIRMA _____

DATA MEDICO _____

TIMBRO FARMACIA

DATA FARMACIA _____

ORIGINALE

1.P.Z.S. - Officina Ditta Valori - P.V. - Roma

Regulatory actions for analgesics

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March 2005: Previous restrictions for reimbursement to specific patient populations (*mild to moderate pain in cancer or in degenerative diseases*) for the combination codeine + paracetamol are abolished and it becomes fully reimbursed in pain treatment by the Italian National Health Service.

October 2009: The same restrictions are abolished for tramadol.

Opioid availability in Western European countries

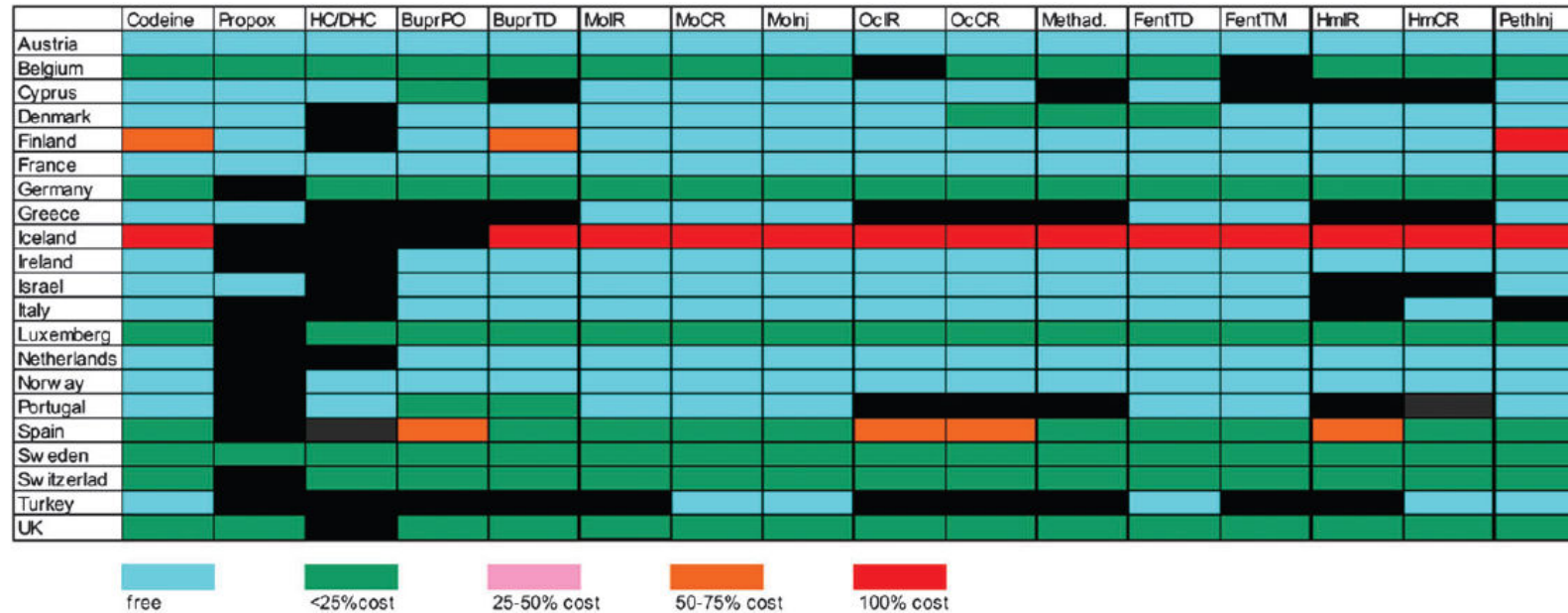
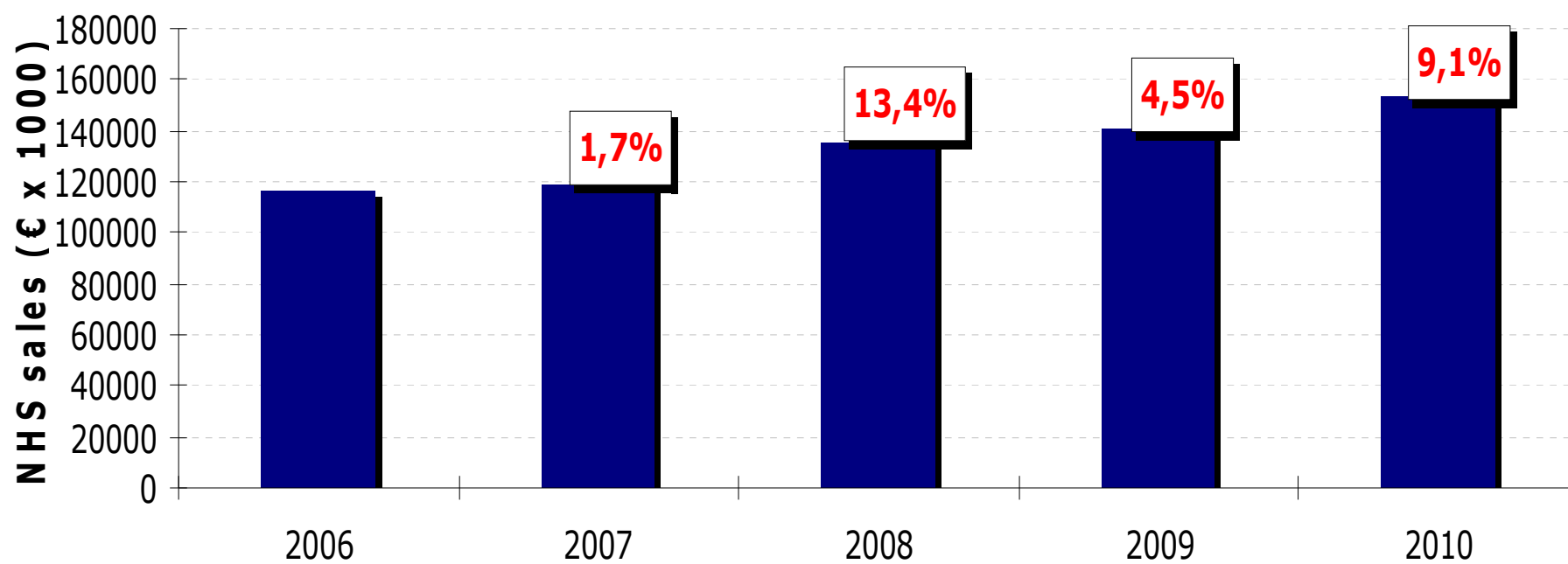


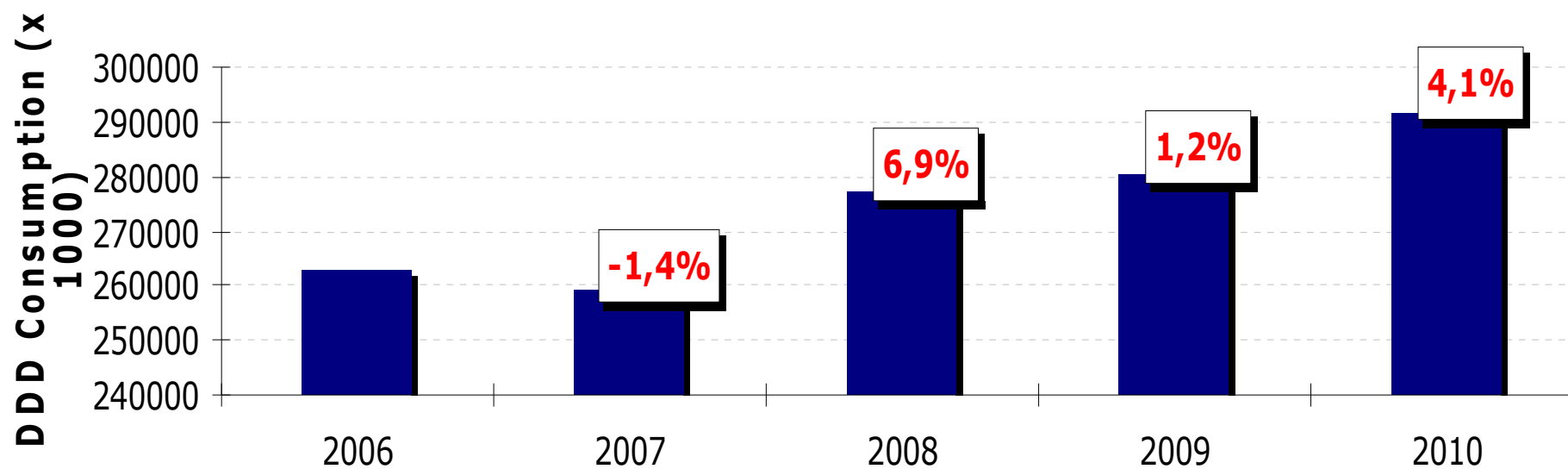
Figure 3. Opioid availability in Western European countries. Propox, propoxyphene; NC, hydrocodone; DHC, dihydrocodeine; Bupr, buprenorphine; Mo, morphine; Oc, oxycodone; Methad, methadone; Fent, fentanyl; Hm, hydromorphone; Peth, pethidine; PO, oral; Propox, propoxyphene; TD, transdermal; TM, transmucosal; Inj, injectable; IR, immediate release; CR, controlled release.

Source: Cherny NI, Baselga J, de Conno F, Radbruch, L. Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative. *Annals of Oncology* (2010) 21: 615–626.

NHS retail expenditure for pain treatment in Italy

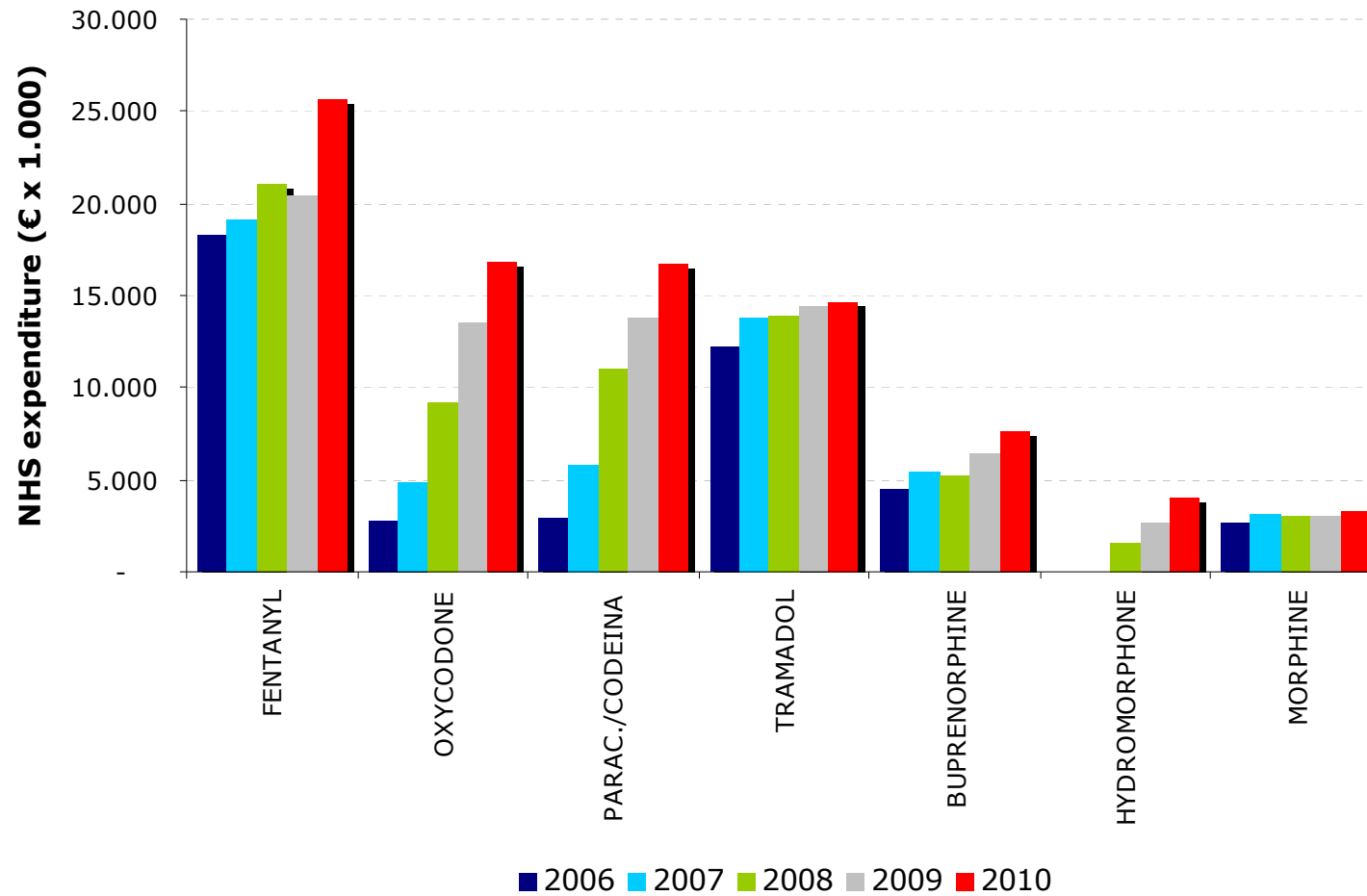


DDD consumption for pain treatment in Italy



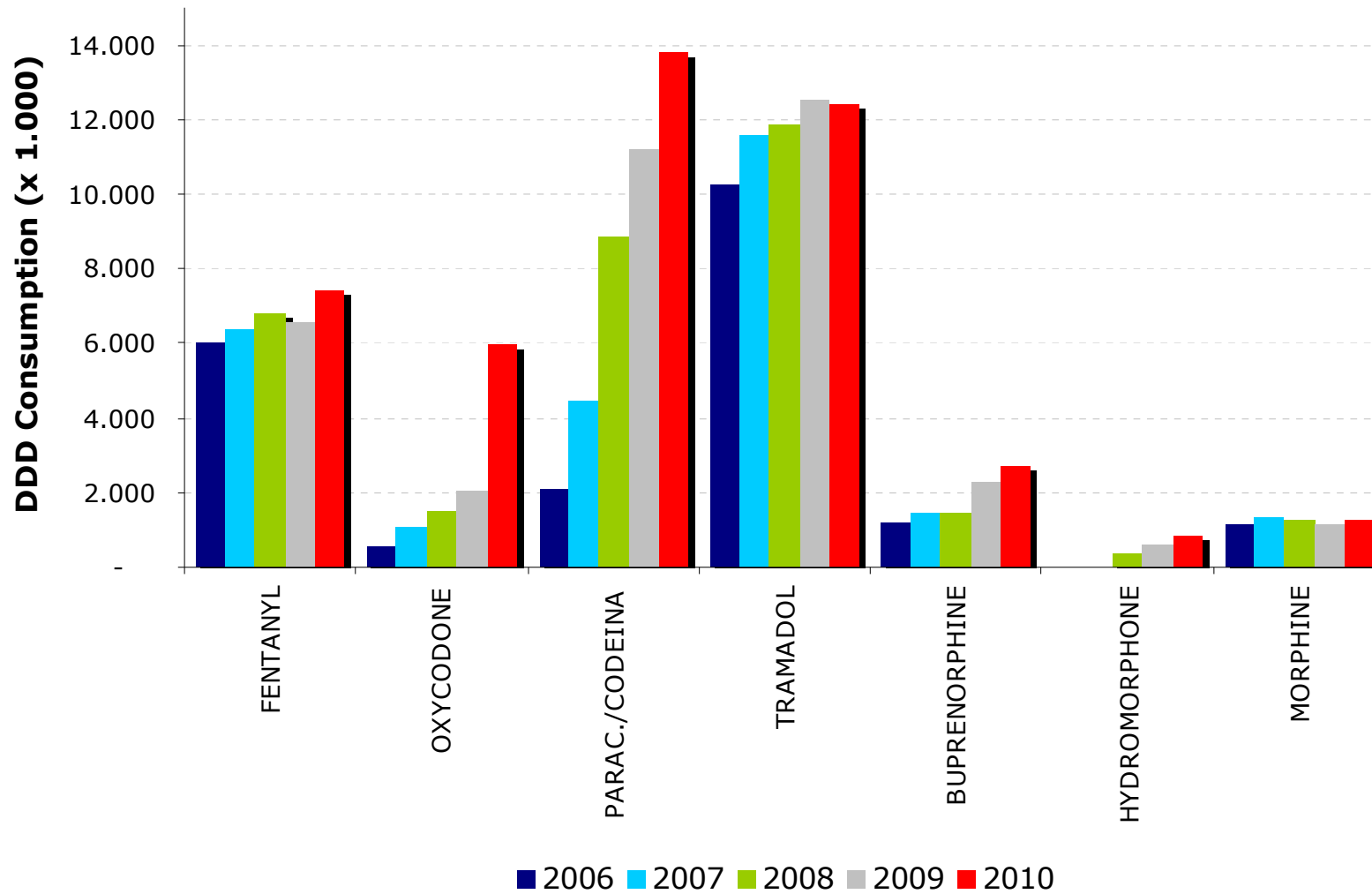
Italian NHS retail expenditure for opioid analgesics

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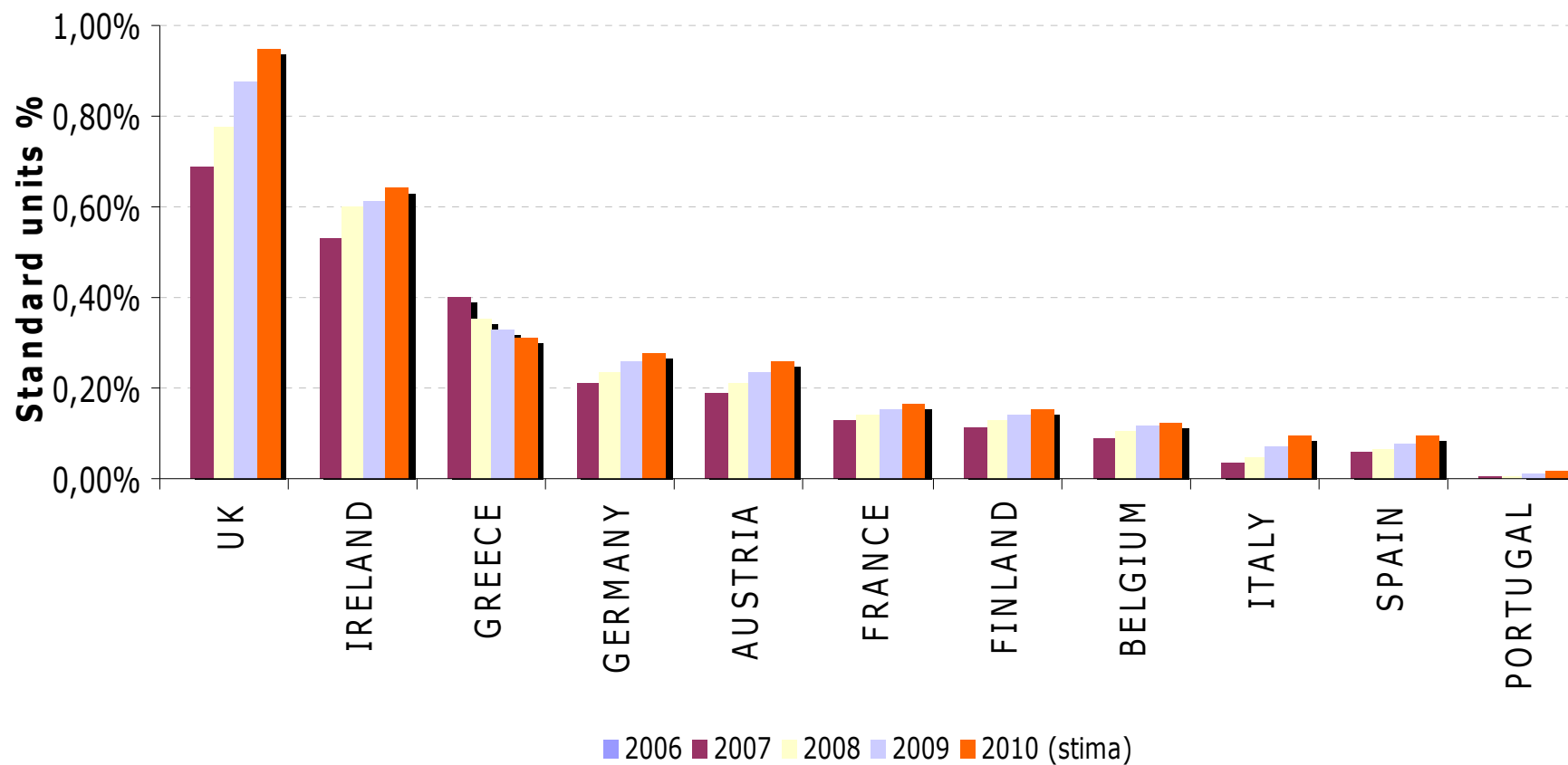


AGENZIA ITALIANA DEL FARMACO

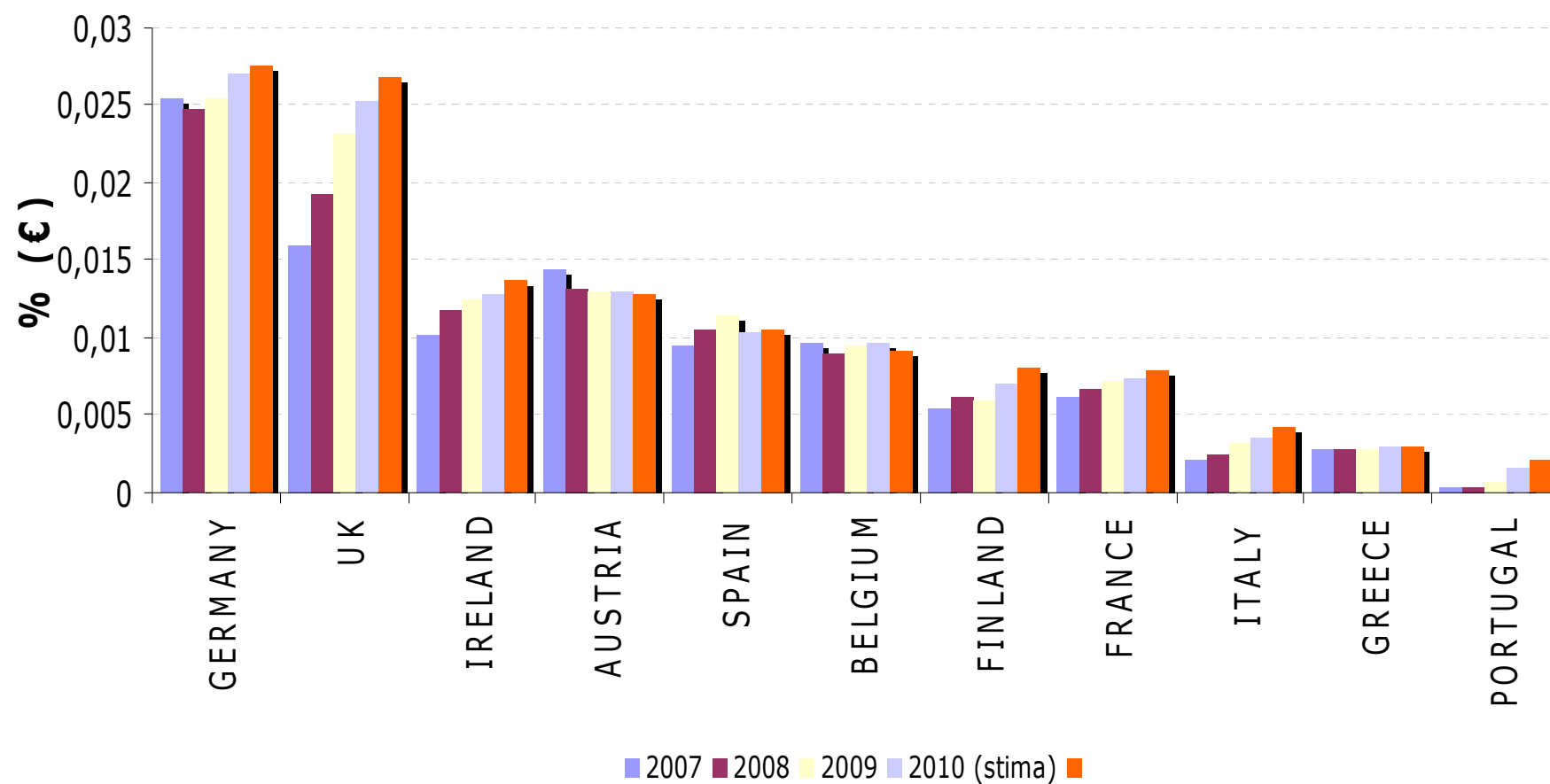
Retail (reimbursed) consumption of opioid analgesics in Italy



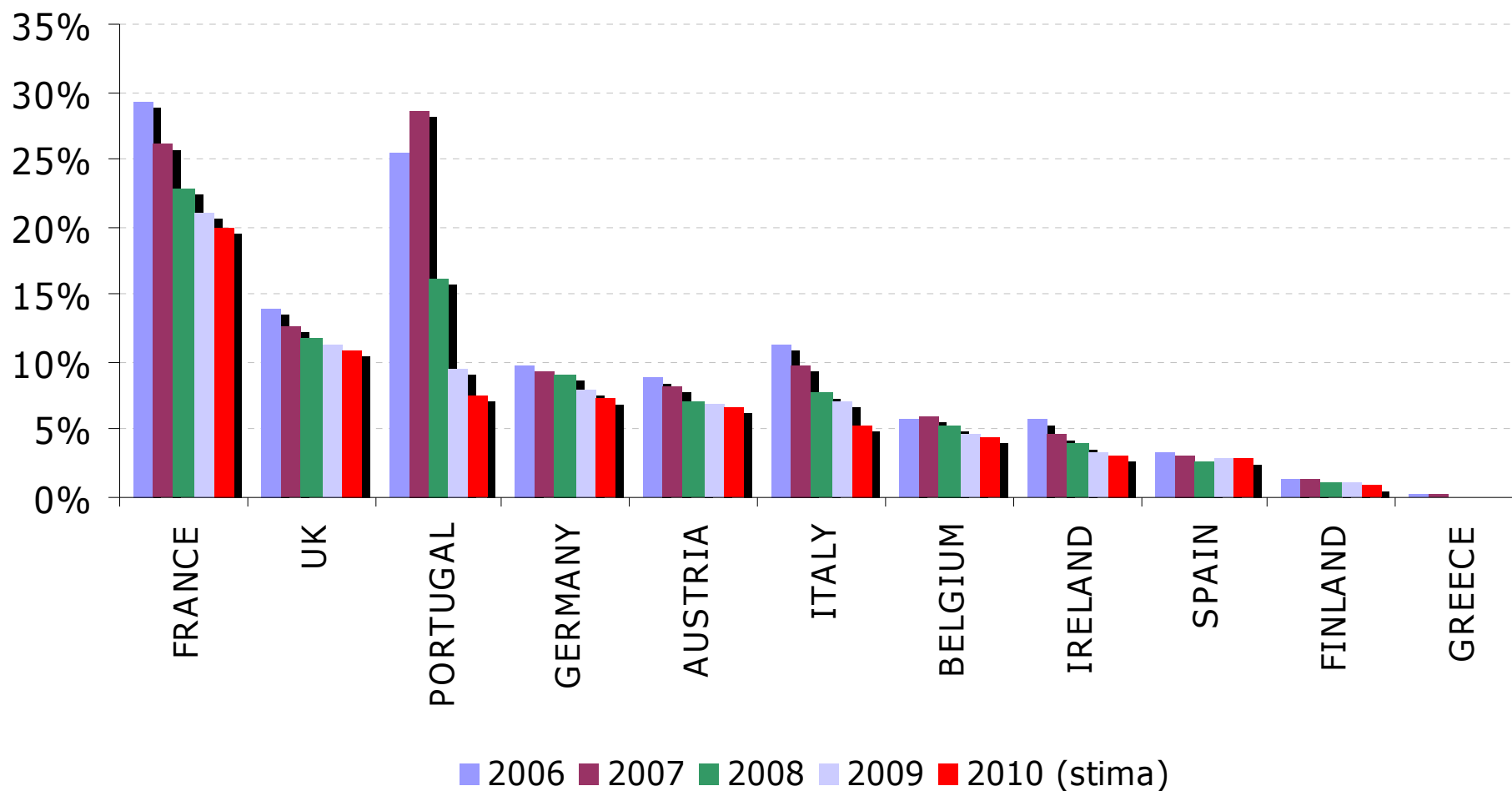
Retail consumption in Standard Units for ATC class N2A0



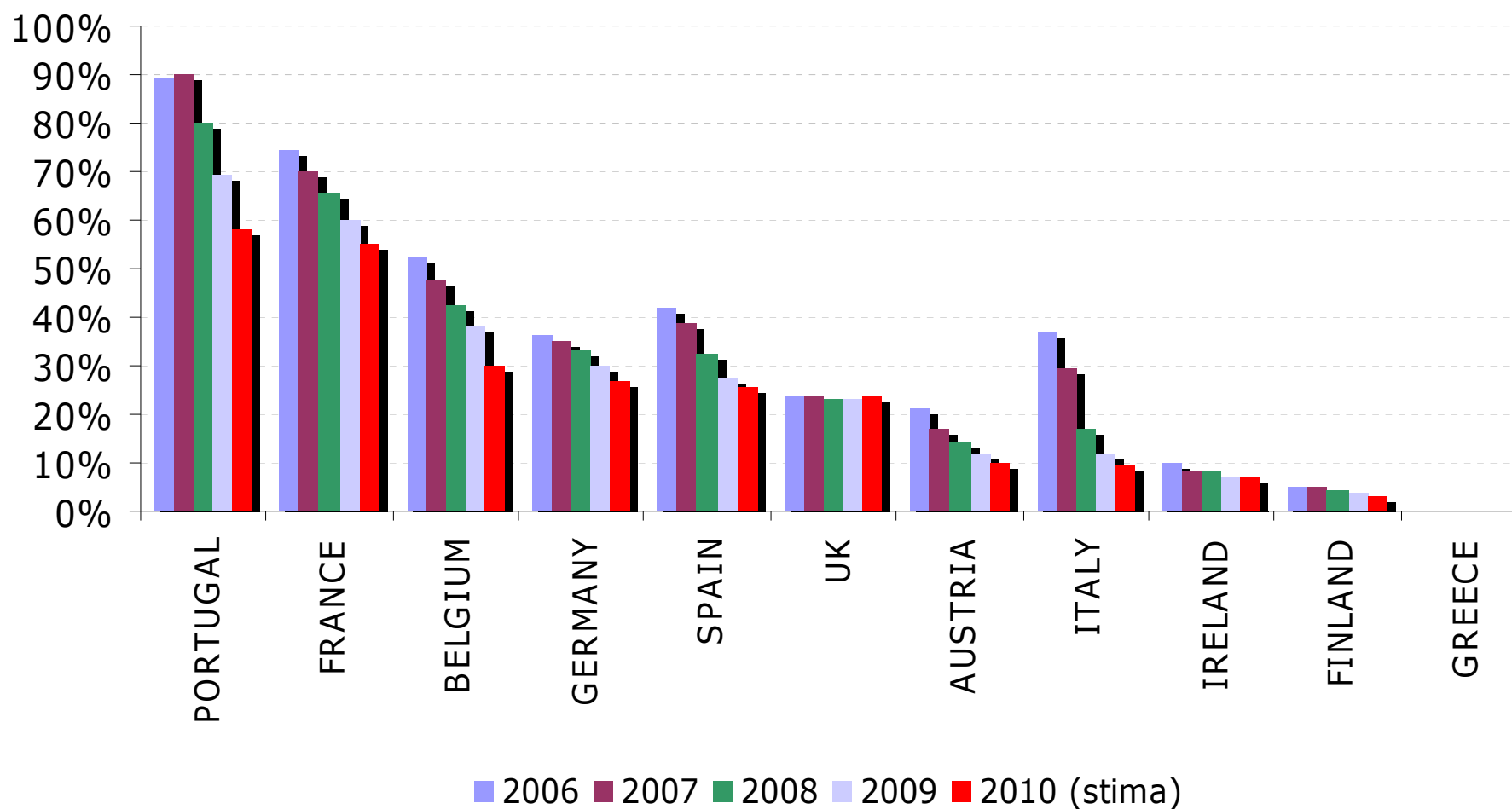
Retail ex factory sales for ATC class N2A0



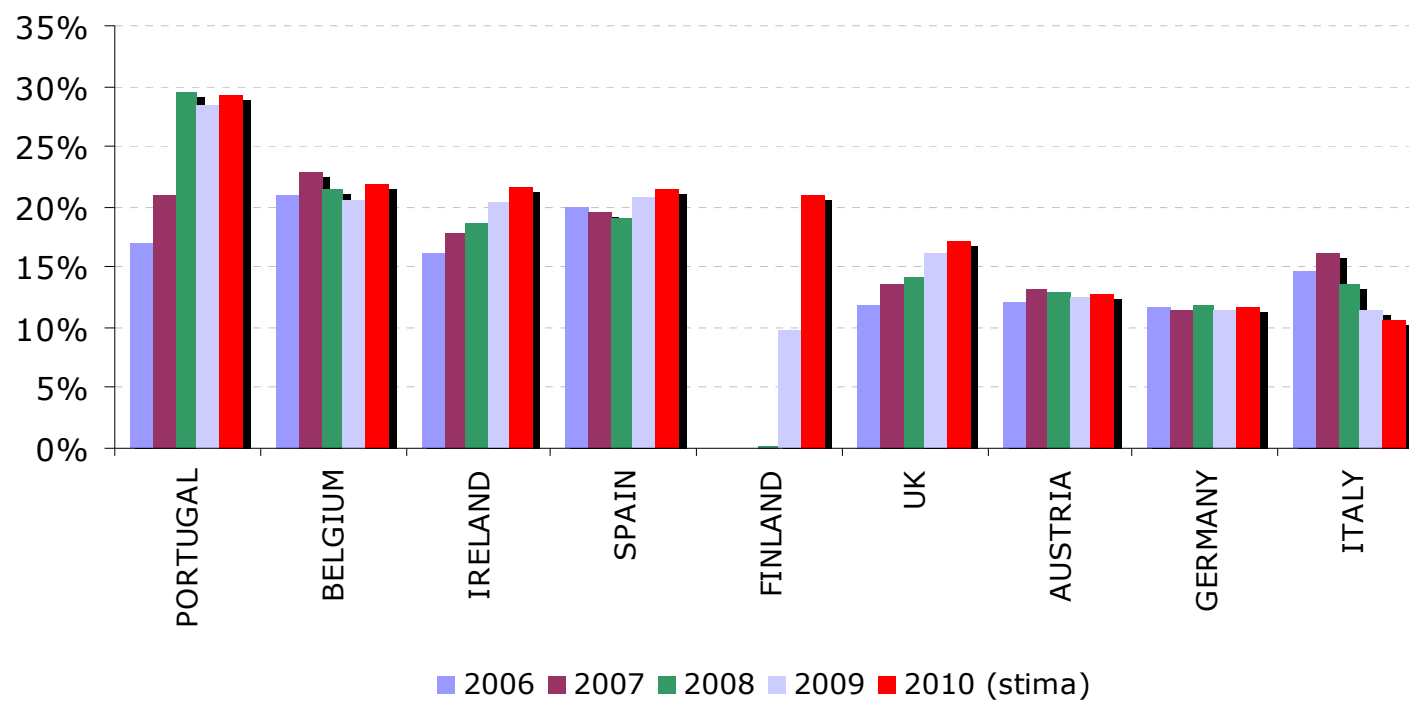
Morphine retail sales (% of N2A0)



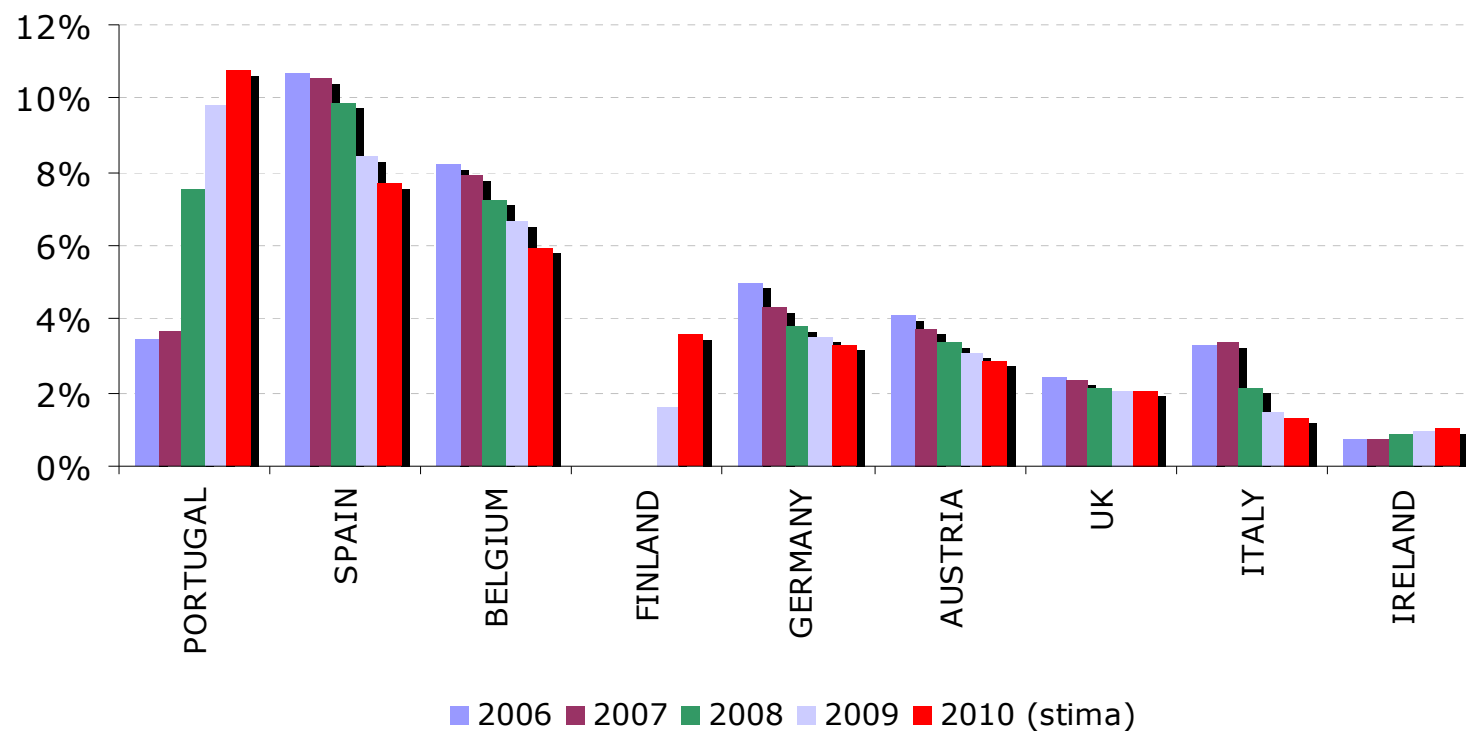
Morphine: standard unit retail consumption (% of N2A0)



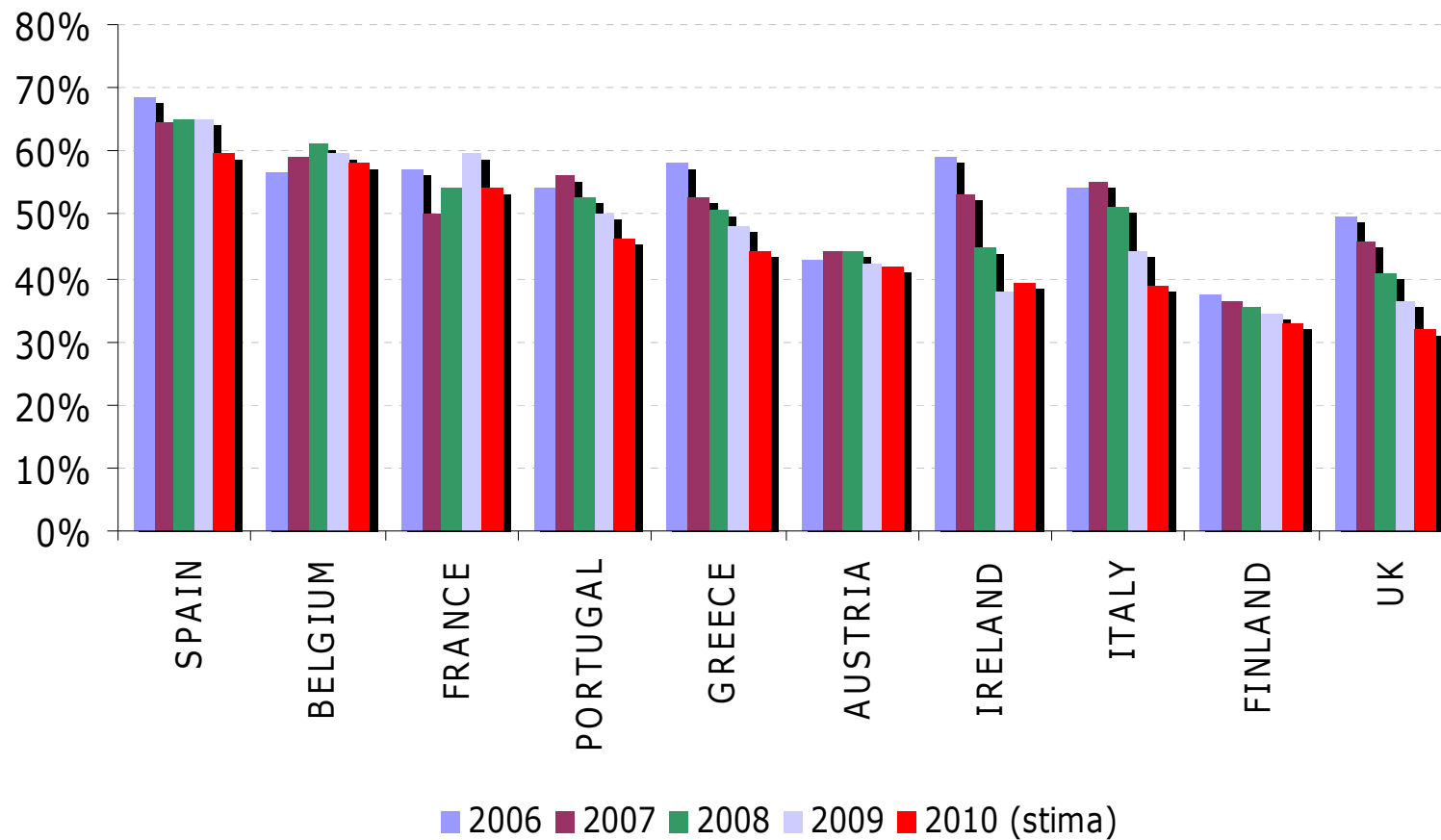
Buprenorphine retail sales (% of N2A0)



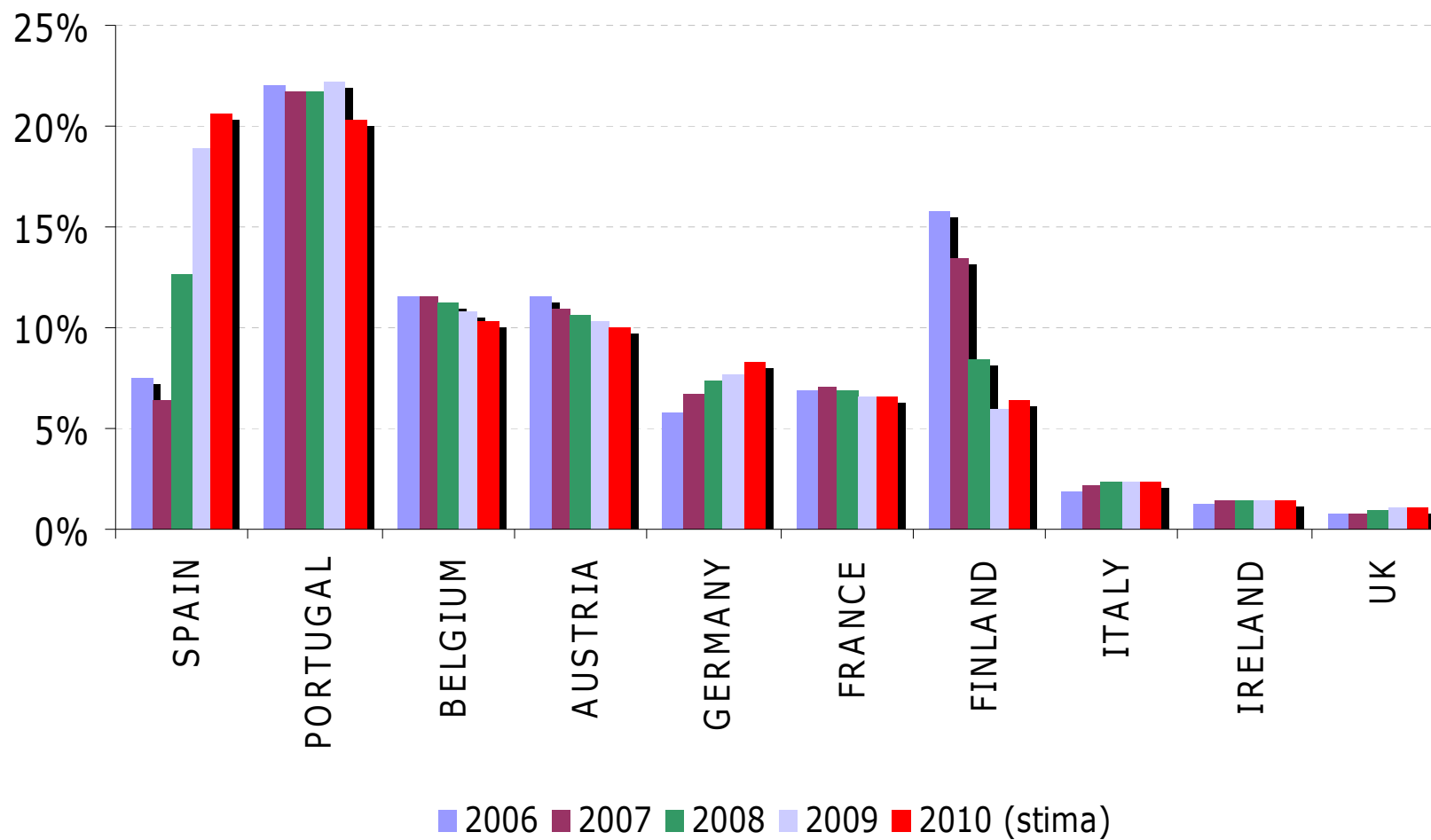
Buprenorphine: standard unit retail consumption (% of N2A0)



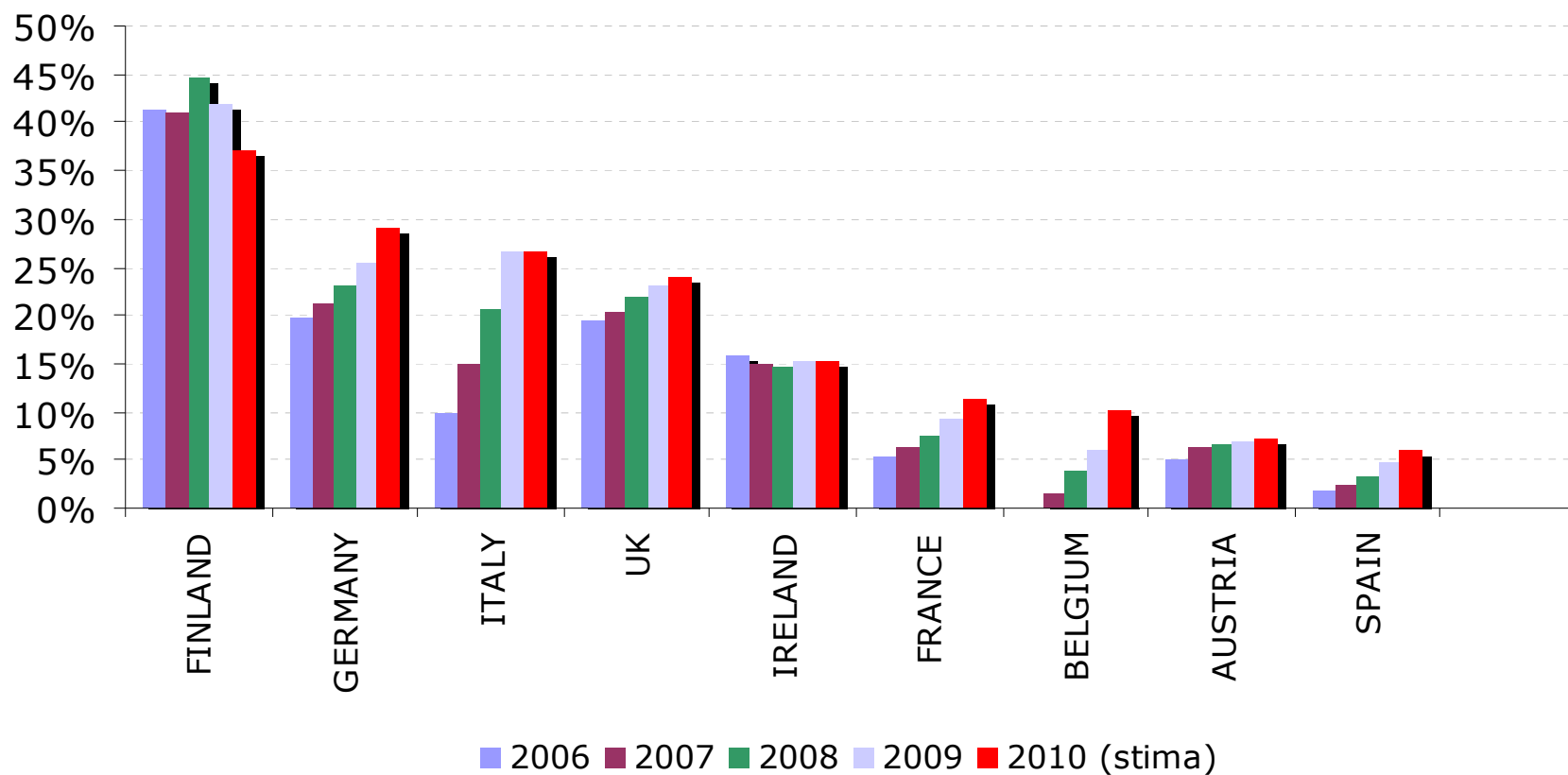
Fentanyl retail sales (% of N2A0)



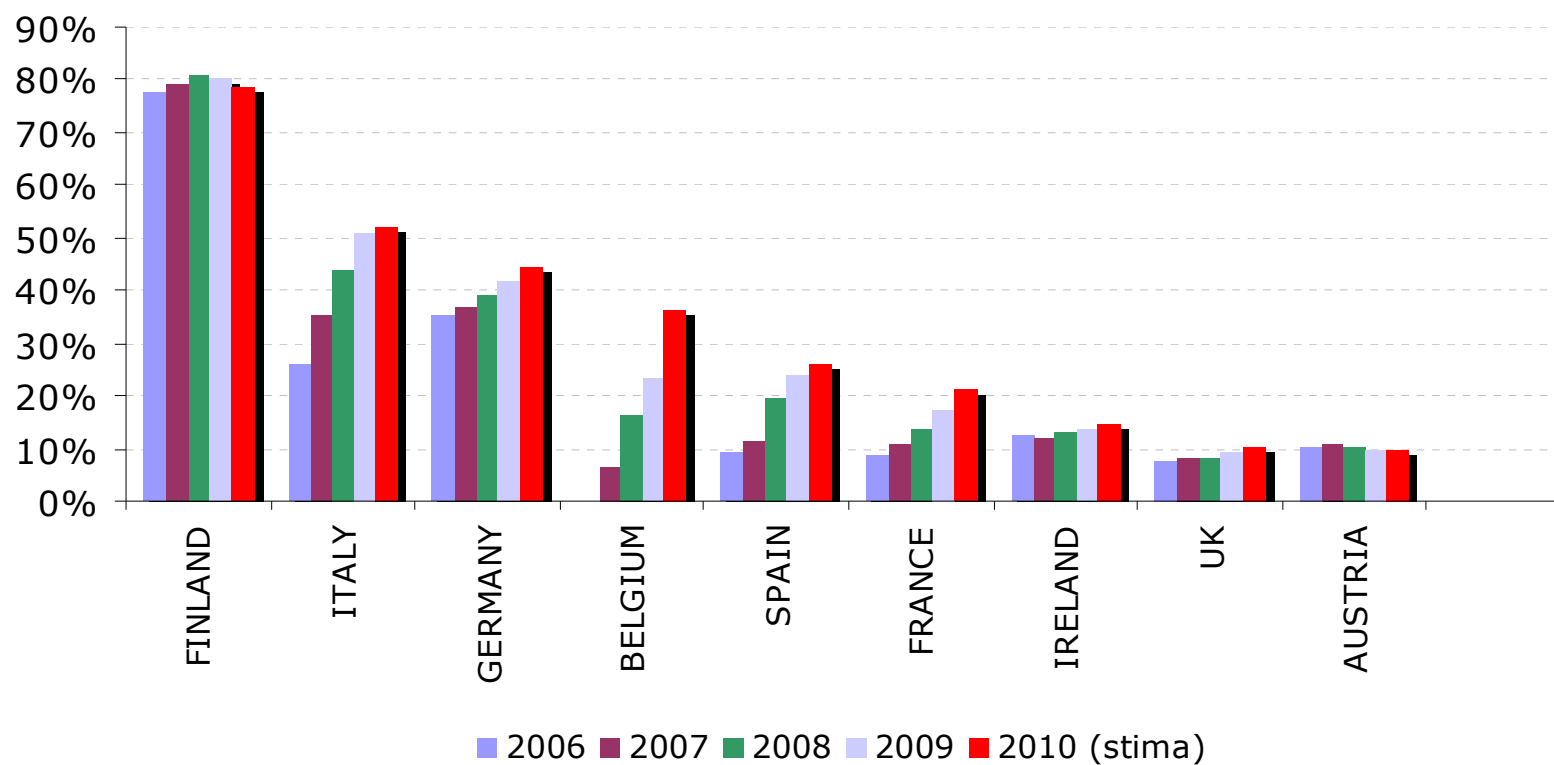
Fentanyl: standard unit retail consumption (% of N2A0)



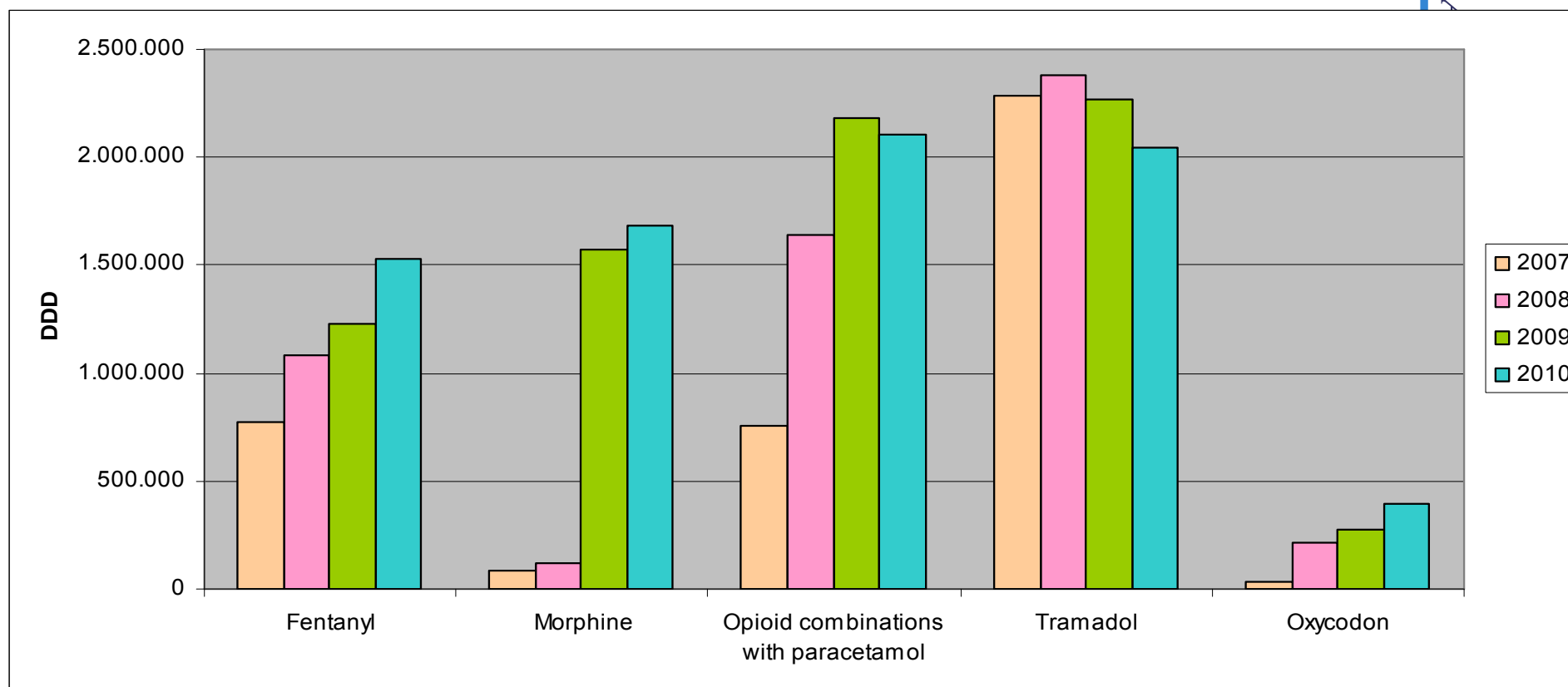
Oxycodone retail sales (% of N2A0)



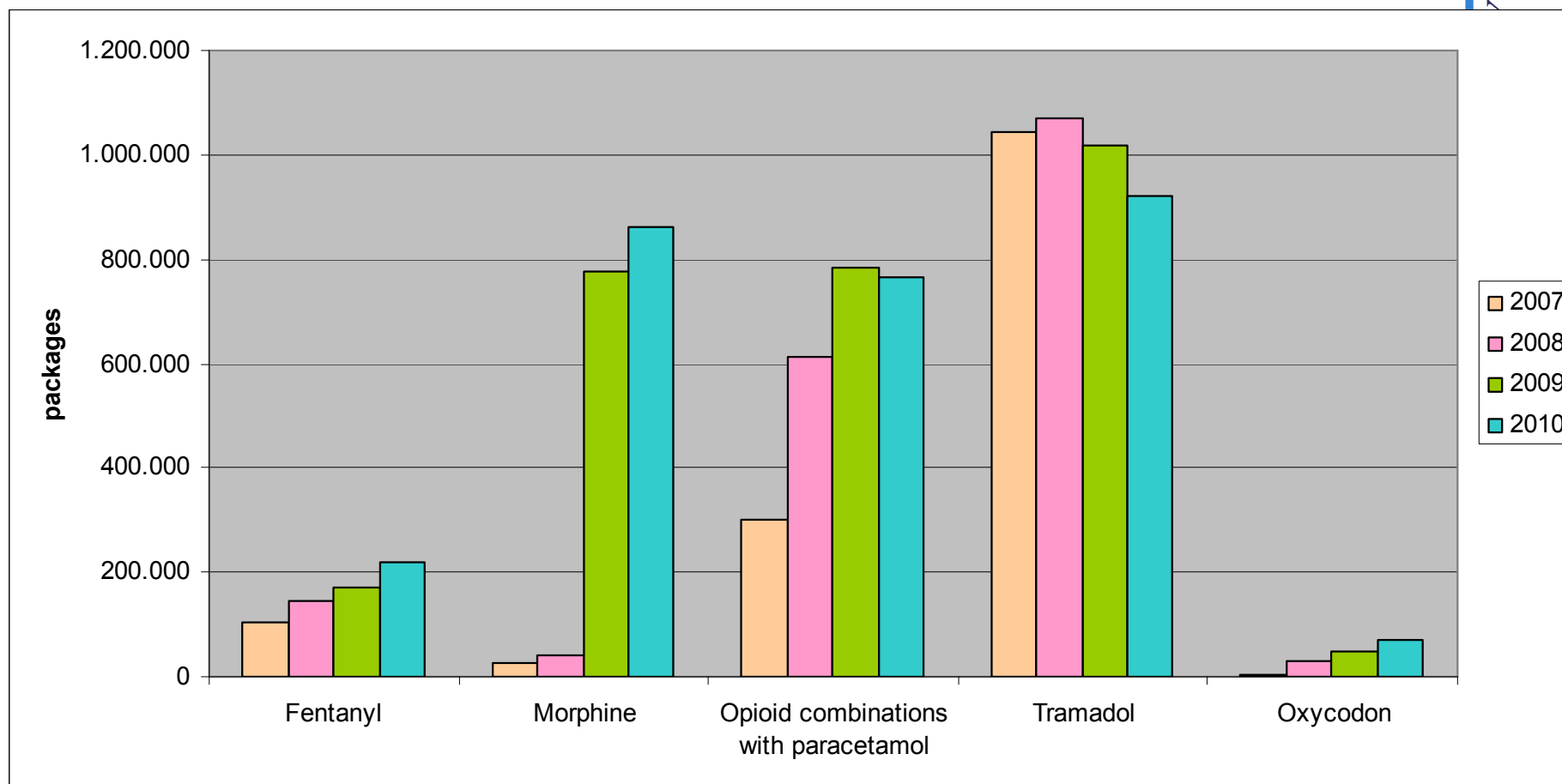
Oxycodone: standard unit retail consumption (% of N2A0)



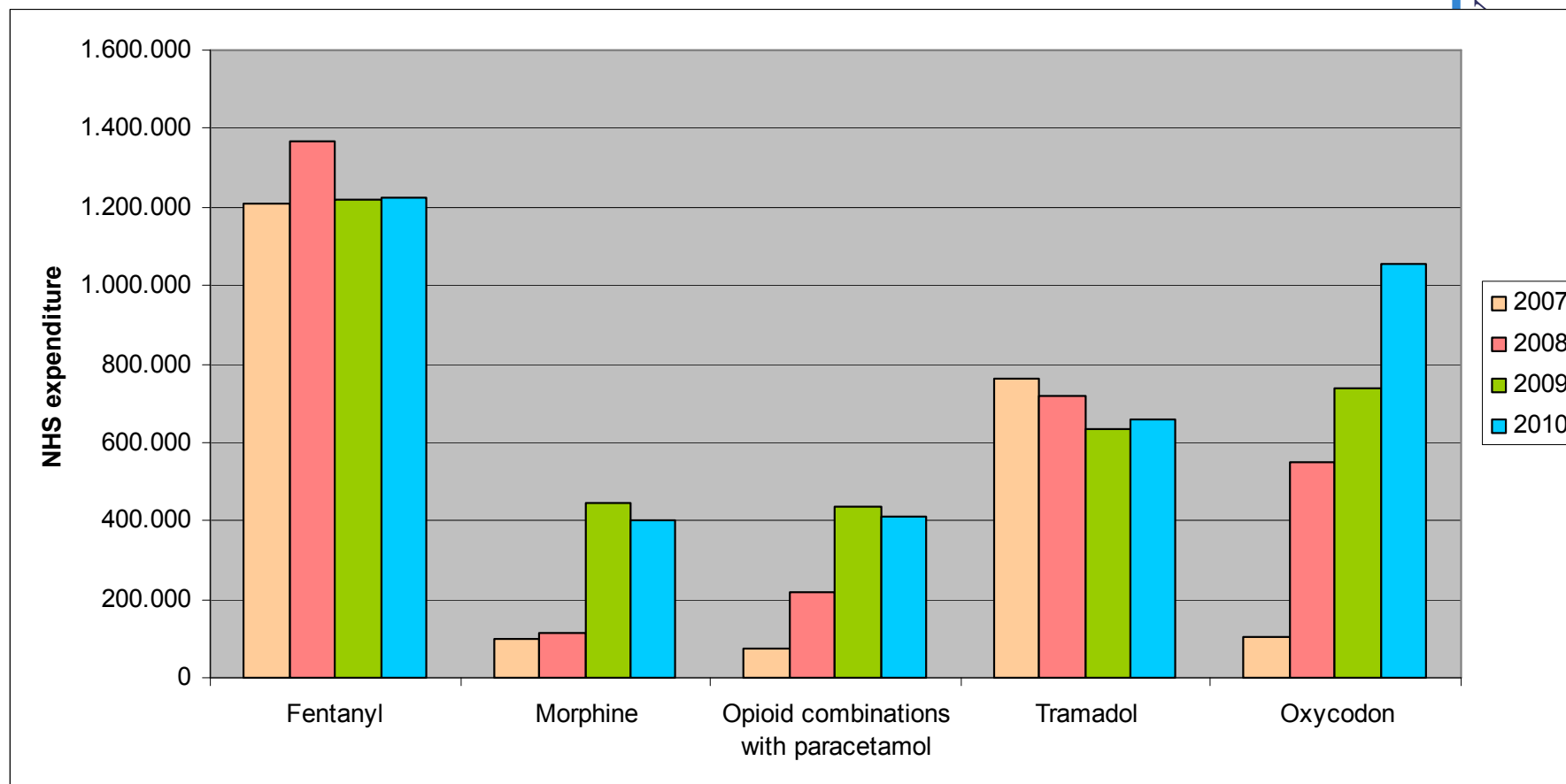
DDD hospital consumption



Hospital packages



NHS hospital expenditure



Conclusions

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- Opioid analgesics consumption in Italy remains lower than in some other EU countries.
- However, the importance of the adopted legislative and regulatory actions is confirmed by the increasing trends in expenditure and DDD consumption.
- Constant monitoring of the impact of the most recent legislation in the effort to align Italy with other EU countries for the treatment of pain.