



The Use of Umbrella Brand Names in Ireland

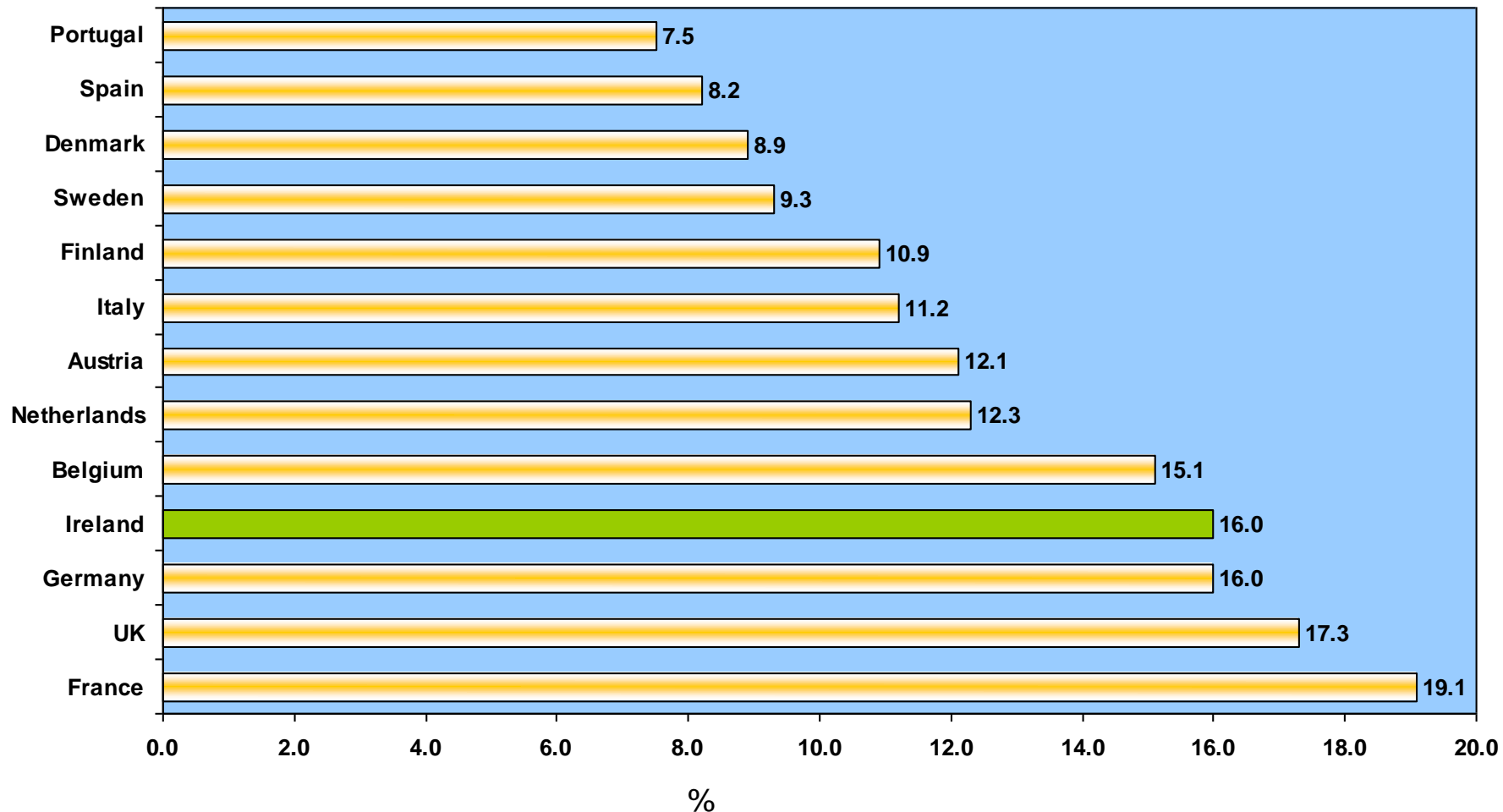
Anne Nolan, B.Sc. (Pharm) M.B.A. M.P.S.I.

AESGP Members Meeting, Madrid, 4 February 2009

IPHA

The Irish **Pharmaceutical Healthcare** Association (IPHA) represents the international research-based pharmaceutical industry in Ireland. Our member companies include both manufacturers of prescription medicines and **non-prescription or consumer health care medicines.**

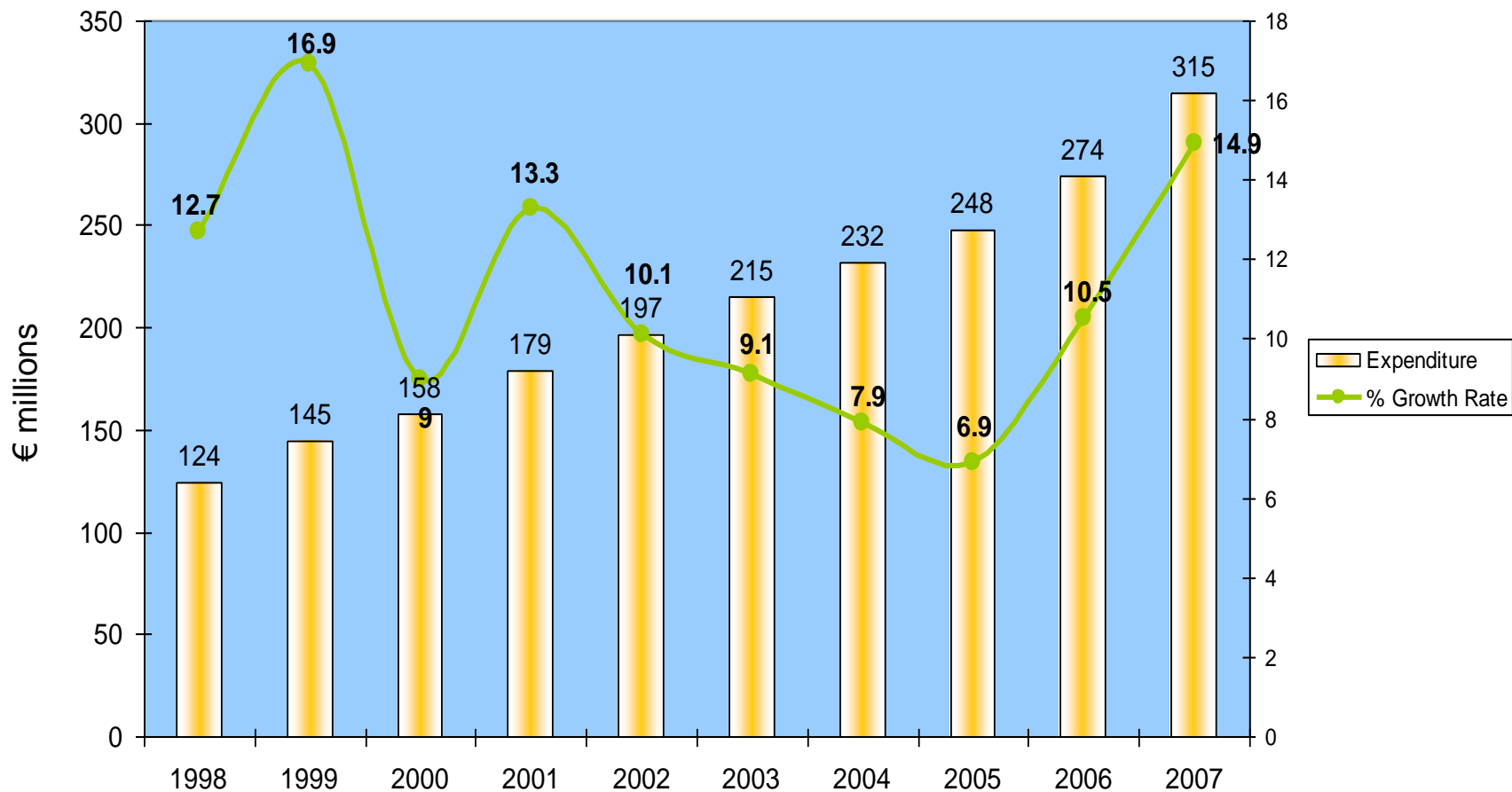
Today, OTC medicines make up a significant element of the Irish Pharmaceutical Market...



Source: AESGP Economic and Legal Framework for Non-Prescription Medicines 2008

www.ipha.ie

...which has continued to grow steadily



Self-medication market in Ireland 2007



Total Market €315 m*

- Analgesics 23%
- Cough & Cold 16%
- Vitamins & Minerals 12%
- Digestives & Intestinal Remedies 10%
- Skin Treatment 10%
- Smoking Cessation 7%
- Others 22%

Umbrella brands in Ireland

No specific legislation

Irish Medicines Board (IMB) “Guide to invented names of human medicines”

Principle of the IMB's guide

Names are acceptable if they are not associated with “perceived public health concerns of a safety risk related to the possibility of **confusion** or to **misleading inferences**”

Principle of the IMB's guide (ctd.)

Recommends avoiding confusion between:

- Products of similar names
- Product names and the INN

Name needs to make adequate distinction

Principle of the IMB's guide (ctd.)

Avoid misleading names with respect to:

- Therapeutic class
- Therapeutic claims
- Active substance
- Pharmaceutical connotations

Suitable and appropriate names required

Irish Medicines Board view

Umbrella names are accepted for OTC products if:

- General therapeutic area is the same for all products
- Umbrella name qualified by a second invented name (e.g. Benylin chesty cough)
- Same active substance (strongly recommended for safety reasons) (See exceptions later)

Example: Rennie



Example: Canesten



Case study 1: Suffixes and prefixes

In 1993, NDAB (now IMB) decided to implement policy changes e.g. suffixes such as **Extra, Plus** “*no longer acceptable*”

IPHA engaged in discussions with the regulator

IPHA representations asserted:

Ultimate decision correctly rests with the company

Role of regulatory authority relates to **quality, safety, efficacy only**

Consumption of product under **normal conditions** of use

No evidence to date that the manufacturers' freedom to choose a particular brand name **jeopardises the safety** of the patient in the correct use of medicines

The results of our efforts:

Suffixes and prefixes still permitted

Umbrella brands exist (within reason)

Applications normally approved

Panadol



Nurofen



Strepsils



Case Study 2: Rx/OTC under same umbrella

Medicines with **different legal status** have been allowed under the **same umbrella brand**

No public advertising of reimbursed products with exactly the same name

Rx/OTC under the same umbrella brand

If advertising, differentiate name:

- new name
- use of a suffix or additional description

Pepcidtwo (OTC version of Pepcid)



Voltarol Emulgel P (OTC version of Voltarol topical)



Lamisil AT and Lamisil Once (OTC version of Lamisil Cream)



Nizoral Dandruff Shampoo (OTC version of Nizoral Shampoo)



Zovirax Cold Sore Cream (OTC version of Zovirax Cream)



Case Study 3: Products with different active substances

Products focused on the **same therapeutic area** with **different active substances** have been allowed to be promoted under the **same brand name**

Benylin

Benylin Children's Dry Cough

➤ active : Diphenhydramine HCL + Levomenthol

Benylin Children's Chesty Cough

➤ active: guaifenesin

WE'VE SPENT YEARS LISTENING TO CHILDREN



THAT'S WHY THERE'S A BENYLIN COUGH TREATMENT FOR EVERY TYPE OF CHILDREN'S COUGH



CHILDREN'S RANGE

ALWAYS READ THE LABEL
ASK YOUR PHARMACIST FOR ADVICE

Children's Chesty Cough



Anadin (aspirin)
&
Paracetamol from the makers of Anadin

Summary

Common objective for industry and regulatory authority:

The promotion of the correct and safe use of the medicine

Conclusion

Umbrella branding is largely taking place in the Irish market

Approach such as to avoid creating confusion among consumers

Work within regulatory constraints to find suitable names within the umbrella brand

Use of umbrella brands is positive

Experience shows:

Umbrella brands are **valuable asset** for companies

Confidence in OTC products enhanced

Within an umbrella range: all products are endowed with a **quality seal**

Recommendations

Industry must adopt a responsible attitude

Work with and challenge the regulatory authority where appropriate

Work with local trade associations

Educate regulatory authorities

Build their confidence

Don't expect everything from day one

Thank you – for more information visit...

www.ipha.ie

www.medicines.ie

www.feelbetter.ie

www.medicinesandyou.ie