



GlaxoSmithKline
Consumer Healthcare



Proven Economic and Social Benefits from Switch Nicotine Replacement Therapy

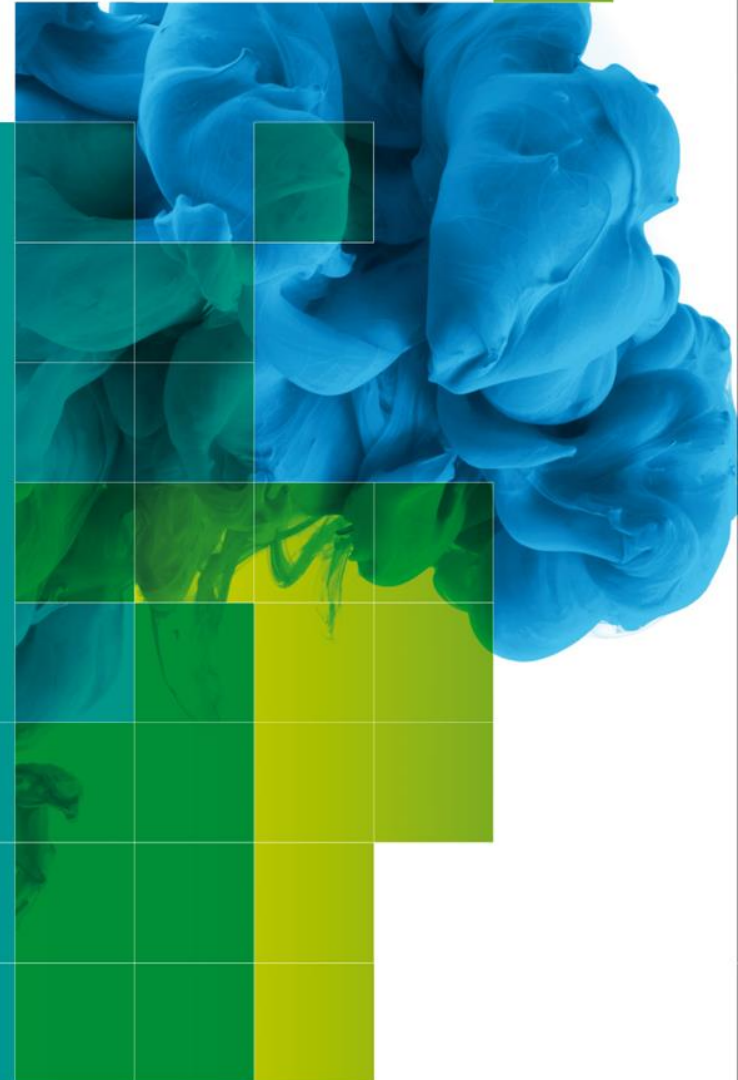
Ian Adams

Vice-President, Regulatory & Quality

Asia-Pacific and Latin America

GSK Consumer Healthcare

WSMI Phuket, October 2014



GlaxoSmithKline Consumer Healthcare

- **A leader in the worldwide consumer healthcare market.**
 - Underpinned by our Science and our Values
 - Four Global Categories
 - Wellness, Oral Healthcare, Nutritionals, Skincare
 - Many Global Brands
 - eg *Panadol, Aquafresh, Sensodyne, Poligrip, Lucozade, Horlicks & NiQuitin*
 - Over £4 billion in yearly sales
 - A presence in >130 worldwide markets.
 - Announced a potential Joint Venture with Novartis Consumer Healthcare

We are dedicated to improving the quality of human life by enabling people to do more, feel better and live longer

Economic and Social Benefits of Switch

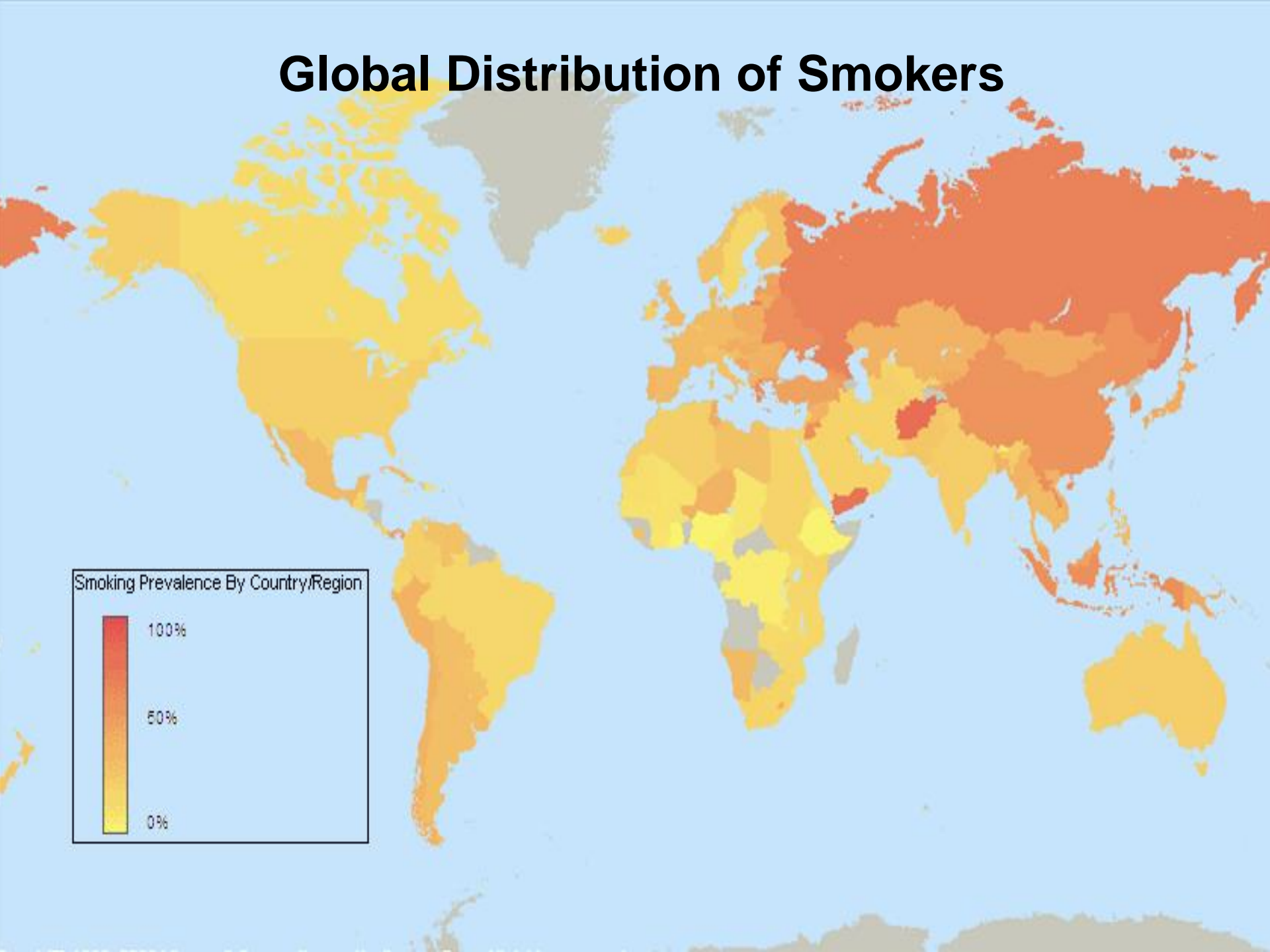
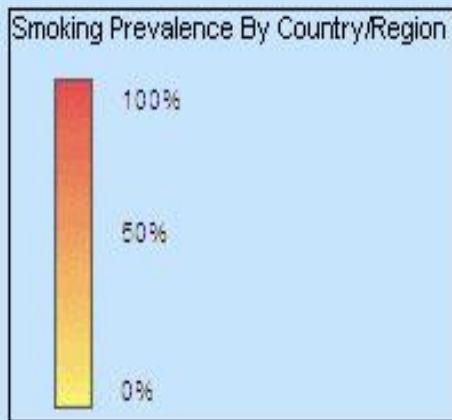
- Increase consumer access to treatments proven to be safe and effective
 - Increase consumer empowerment and knowledge (Self care)
 - Build engagement between consumers and healthcare professionals
 - Reduce healthcare system costs
- “ People want to have a more active role in their own healthcare, including the decisions about what medicines to take. When it comes to access to self-medication, good information and support translate into empowered patients who can benefit fully from the opportunities of self-care and who can practise it safely and effectively with informed choice.”*

Report of the EU Working Group on promoting good governance of non-prescription drugs in Europe, June 2013

Economic and Social Benefits of Switch (2)

- What would happen if current OTC Categories were no longer available?
 - Increase of US \$102bn in direct and indirect costs in the US across 7 categories (Booz Allen 2013)
 - Increase of >AUS \$10bn in direct and indirect costs in Aus across 8 categories, including smoking cessation (Macquarie University 2014)
 - Similar studies carried out in France, UK, Spain, Netherlands, Italy in recent years

Global Distribution of Smokers



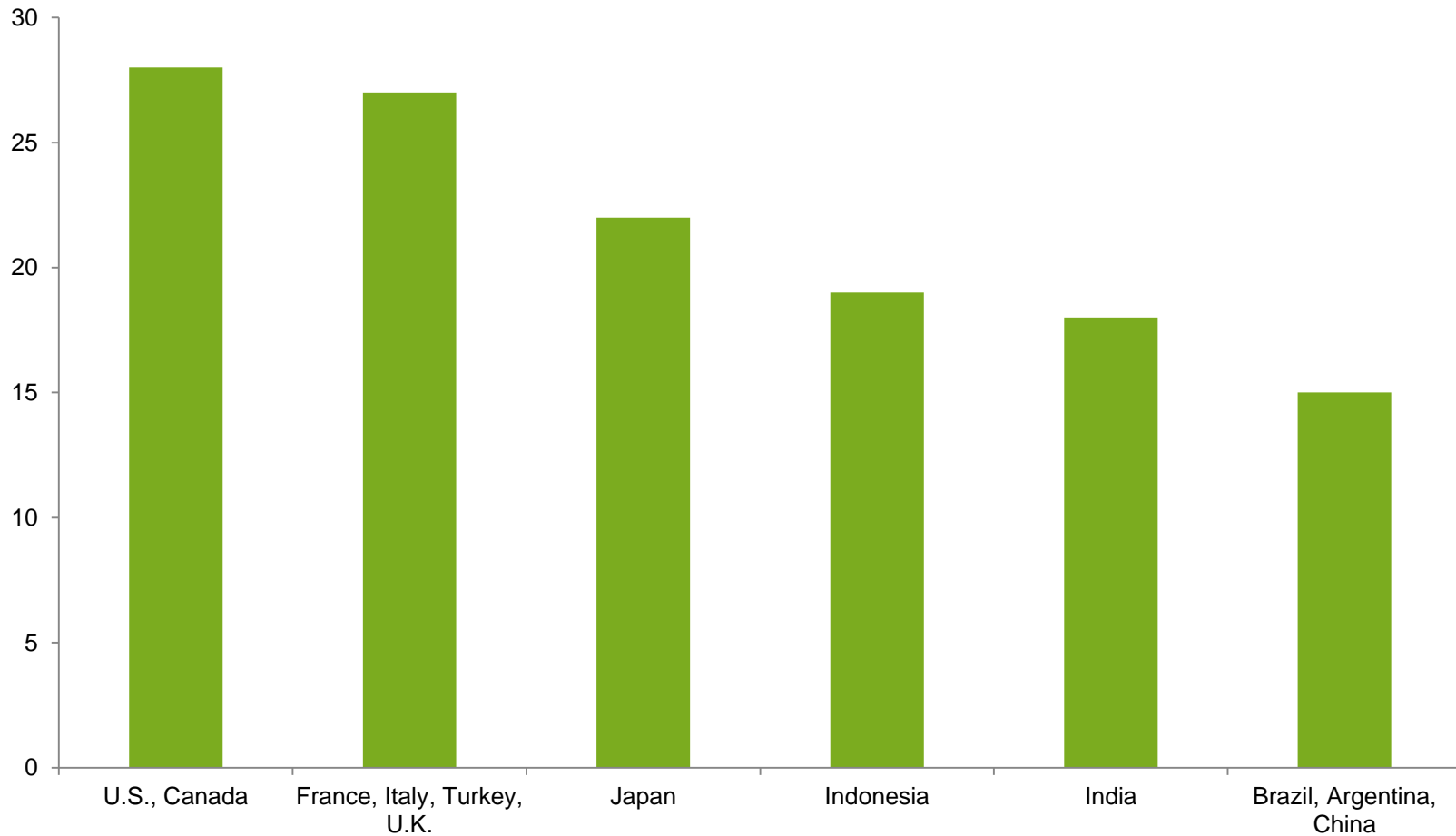
The burden of smoking related disease



- Tobacco use is the leading preventable cause of death globally, killing up to one half of the people who use it.
- If current global trends continue, it is estimated that tobacco will kill more than 8 million people annually by 2030 (approx 75% in low and middle-income countries).
- One third of the world's smokers reside in the WHO Western Pacific Region, where it is estimated that two people die every minute from a tobacco-related disease.
- Approximately 125 million or 30% of all adults in South East Asia are current smokers with tobacco consumption increasing and
 - one of the highest rates of male smoking prevalence,
 - high prevalence in some ethnic groups, low socio-economic groups and rural populations,
 - the fastest increase of tobacco use uptake by women and young people, and
 - increasing second-hand smoke issue for children.

A Global Epidemic

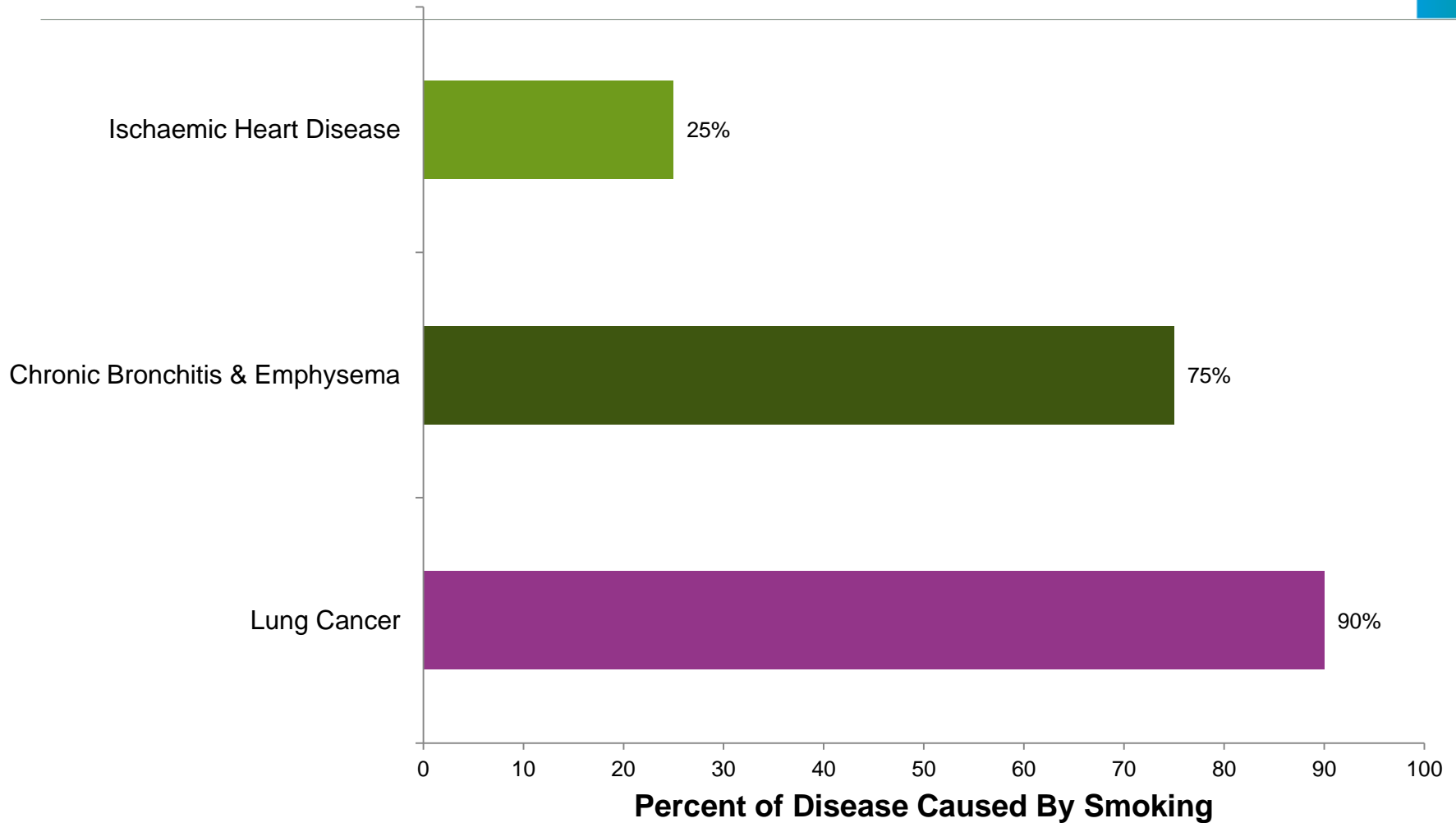
Percentage of deaths from tobacco use



World Health Organization. Tobacco Atlas. World Health Organization Tobacco Free Initiative. 2010. Derived from: Ezzati M, Lopez AD. Estimates of global mortality attributable to smoking in 2000. Lancet 2003; 362: 847-852

A Global Epidemic

Burden of disease from tobacco use



Health Consequences of Smoking and Quitting



- **Quitting smoking reverses health risk**
 - Some quickly (e.g., sudden cardiac death)
 - Some slowly (e.g., cancer)
 - Stops progression (e.g., emphysema)
- **But it isn't easy....**
 - 40% of smokers resume smoking after an MI
 - 1/3 of cessation efforts do not last 2 days
 - Many smokers need >5 attempts to quit
 - Most smokers experience nicotine withdrawal

WHO Action Plan/Global Strategy (2008-13)

Prevention and Control of Non-Communicable Diseases

- *“Today, non-communicable diseases (NCDs), mainly cardiovascular diseases, cancers, diabetes and chronic respiratory diseases, represent a leading threat to human health and development.*
- *These four diseases are the world’s biggest killers, causing an estimated 35 million deaths each year – 60% of all deaths globally – with 80% in low- and middle-income countries.*
- *“These diseases are preventable. Up to 80% of heart disease, stroke and type-2 diabetes and over a third of cancers could be prevented by eliminating shared risk factors, mainly tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol.”*

Initiatives to Reduce Smoking Prevalence



****Increase availability, accessibility and affordability of NRT and other effective pharmaceutical interventions**

*WHO REGIONAL ACTION PLAN FOR THE TOBACCO FREE INITIATIVE
IN THE WESTERN PACIFIC (2010–2014)*



History of Nicotine Replacement Therapy

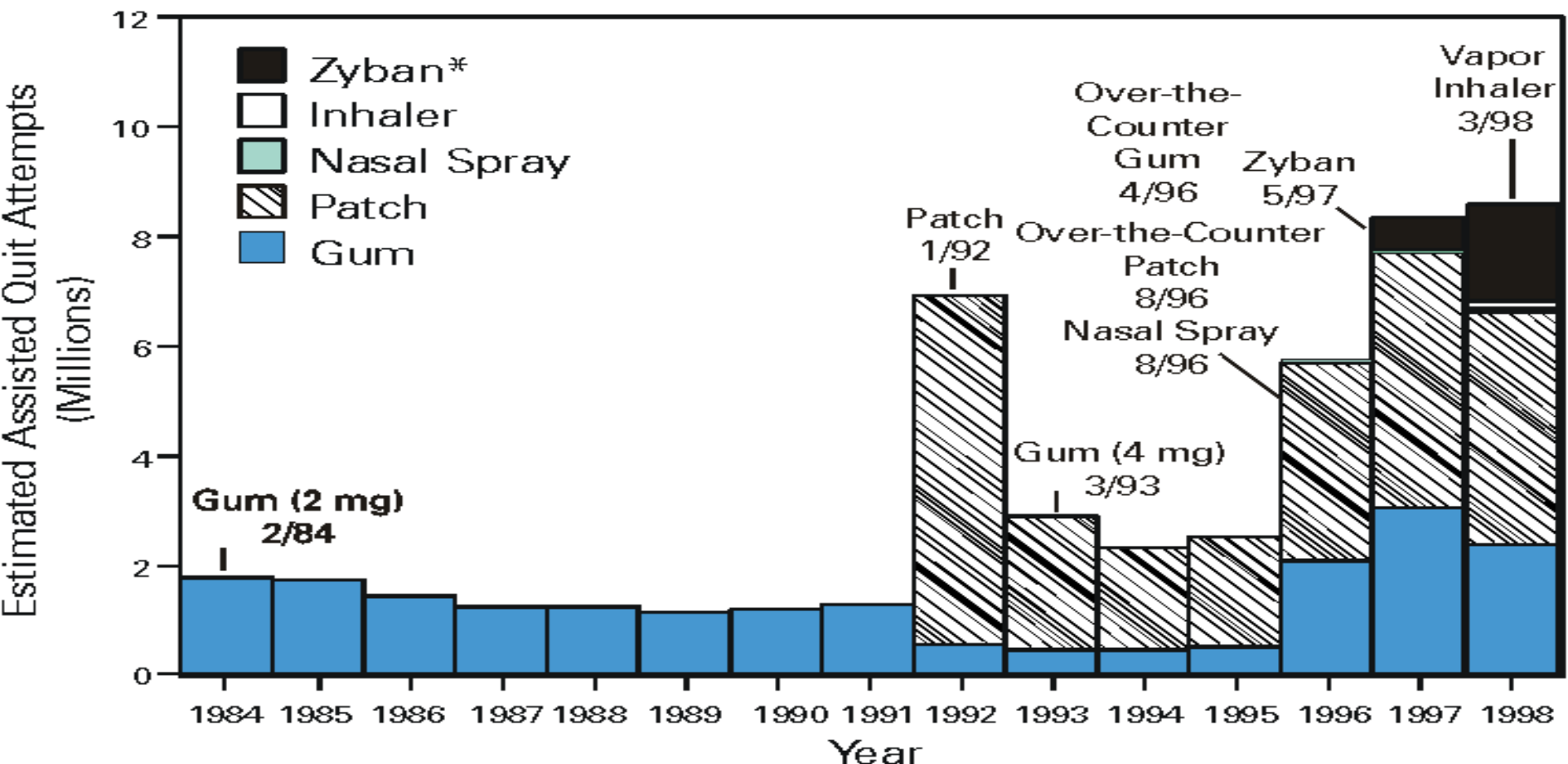
- **First US Rx Launch in 1984 (2mg Gum) followed by Patch in 1992**
- **First OTC launch in 1996 (Gum & Patch)**
- **Available in >130 countries**
- **Proven efficacy and safety of NRT when used as directed.**
 - **Hundreds of clinical trials involving more than 35,000 participants**
 - **Extensive consumer use for more than 20 years have**
- **NRT products have helped millions of smokers quit by gradually weaning them off of their tobacco addiction and is recommended as a first-line therapy for quitting.**

■ ²Stead LF, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. Cochrane Database of Systematic Reviews 2008, Issue 1.

■ Fiore MC, Jaén CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

Trends in Use

FIGURE 1. Use of pharmacologic aids to smoking cessation, by year, and month aid was introduced — United States, 1984–1998



* Use of trade names and commercial sources is for identification only and does not constitute endorsement by CDC or the U.S. Department of Health and Human Services.

Benefits of US NRT Switch



- **Markedly increased access post switch**
 - 78-92% increase in patch use
 - 180% increase in gum use
- **Number of Quit attempts was estimated to double**
 - 2.5 m in 1995 (before switch)
 - 5.7 m in 1997 (after switch)
- **Sustained Utilisation due to ongoing communications**
- **Net annual social benefits of USD \$ 1.8-2bn**

Keeler et al, (2002) Health Economics; 11(5) 389-402

Shiffman & Sweeney (2008) Health Policy; 86, 17-26



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United Kingdom Widening Access to Self-Care Public Health Benefits of Switch

UK Regulatory or Policy Change	Date
Nicotine gum (2 mg) available general sale (GSL)	March 1999
Introduction of treatment for smokers throughout England free through the NHS	April 2000
Bupropion available on NHS prescription	June 2000
All smoking cessation products available on NHS prescription	April 2001
Nicotine gum (4 mg), nicotine lozenge, and all nicotine patches available for GSL	May 2001

Successful National Public Health Policies

Increased NRT access and broader UK Initiatives

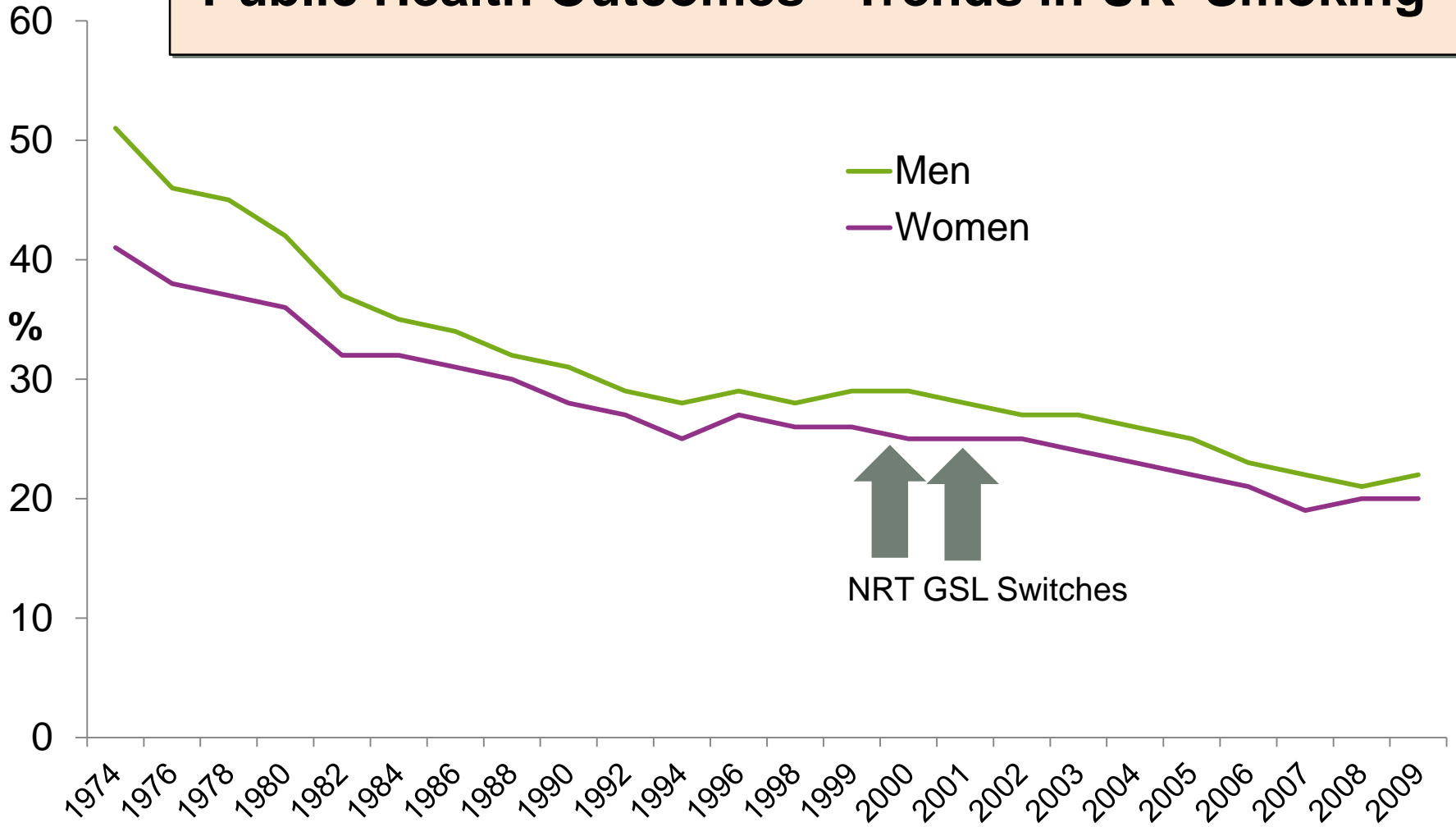


- Cigarette tax increases
- Clean indoor air laws
- Advertising restrictions
- Product labeling
- Mass media policies
- School education programs
- Youth access enforcement
- Access to cessation treatments
- Telephone quit lines

Levy DT, Chaloupka F, Gitchell JG. The effects of tobacco control policies on smoking rates: a tobacco control scorecard. *J Public Health Management Practice* 2004;10(4):338-353.

World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011. World Health Organization. 2011

Public Health Outcomes - Trends in UK Smoking



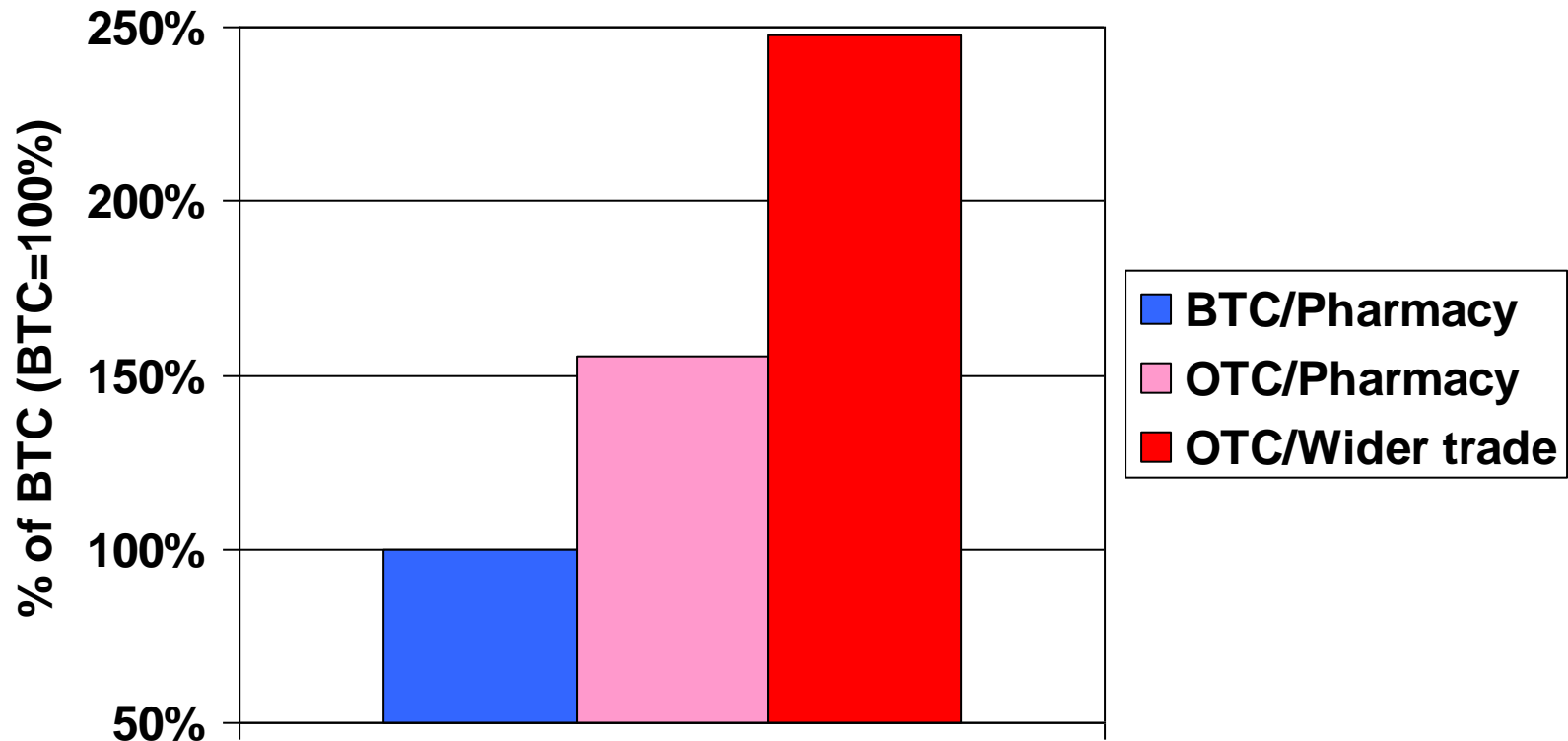
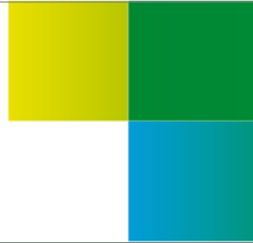
Progress of UK Initiatives



- Dramatic increase in sales of medications to aid smoking cessation
- Widening general sales access was associated with increase in sales
- Significant effects of making bupropion and NRT reimbursable
- Making NRT reimbursable on NHS prescription increased prescription sales without evidence of decline in OTC use
- Significant increase in total sales following launch of new NRT formats (eg, lozenge)

West R, DiMarino ME, Gitchell J, McNeill A. The impact of UK policy initiatives on use of medicines to aid smoking cessation. *Tobacco Control* 2005 Jun;14(3):166-71.

Increased Utilization in Australia Moving NRT from BTC to OTC



Source: GSK Australia, 2002-2007

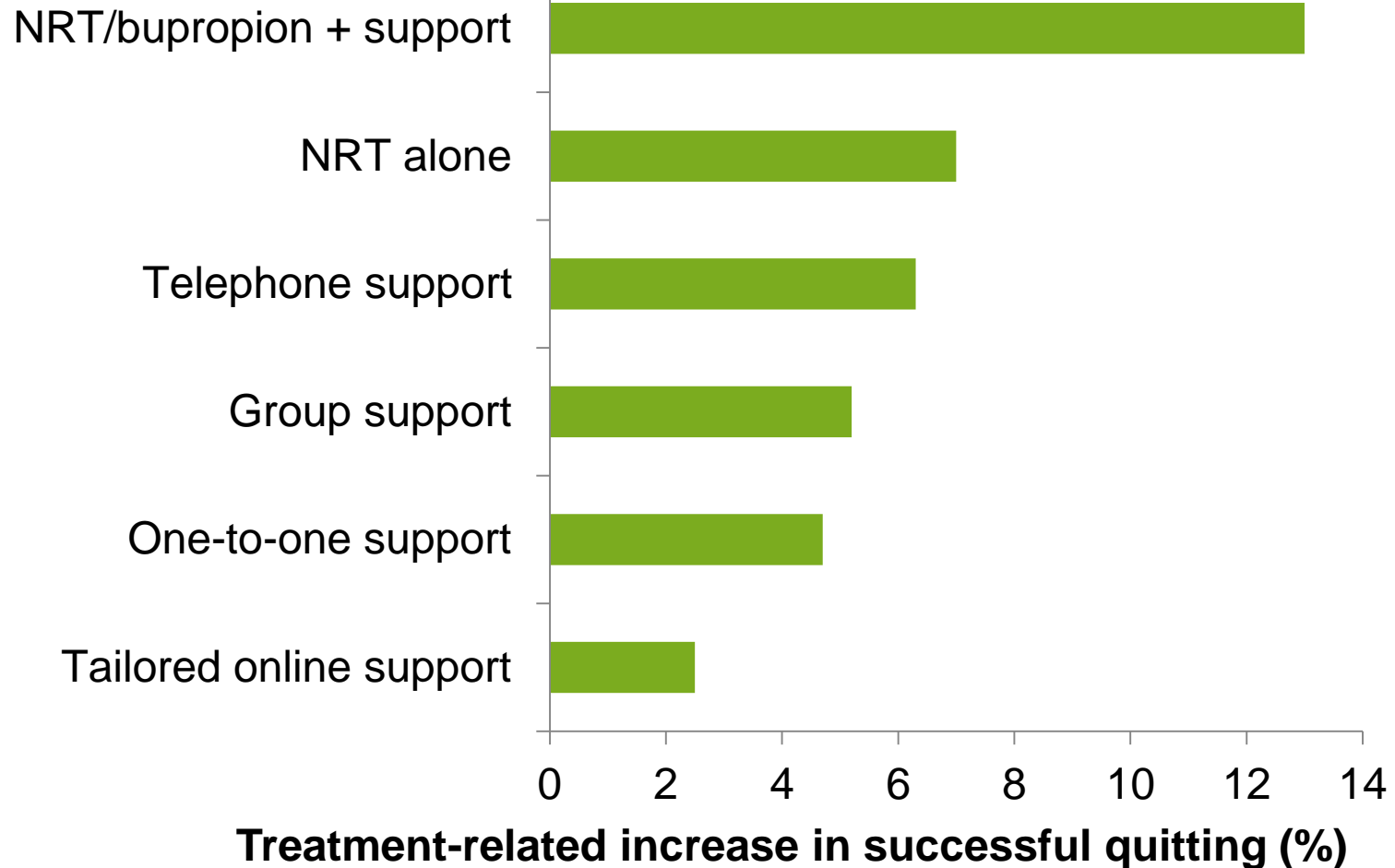
Increased Utilization in Australia

Moving NRT from BTC to OTC



- Smoking prevalence has continued to fall in Australia as a result of a range of complementary and innovative initiatives; eg
 - Graphic pictures and plain cigarette packaging
- Estimated > 68,000 successful quitters and premature deaths have been prevented in the ten years since NRT switch in Australia

Effective Use of NRT



West R, Shiffman, S. Fast Facts: Smoking Cessation. 2007. Health Press.. Oxford, UK

Effective Use of NRT



- Smokers harbor misperceptions about the safety of NRT because it contains nicotine; however, using NRT products to quit smoking is far safer than continuing to smoke.
- Smokers need to be educated about NRT and the role it can play in helping to reduce and eliminate a smoker's dependence on nicotine from cigarettes.
- There is evidence to suggest that providing accurate efficacy and safety information can increase a smoker's willingness to use NRT as part of a quit attempt.

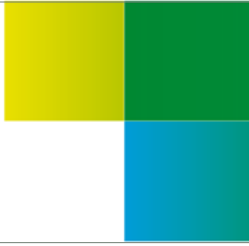
Hughes JR, Keely J, Naud S. (2004) *Addiction*, 99, 29-38.

Survey of 900 adult smokers in the U.S. conducted by American Legacy Foundation and GSK Consumer Healthcare (Aug 2007)

OTC Switch of NRT – For & Against

Table 1
Arguments for and against the Rx-to-OTC switch of NRT

Issues	Findings
Arguments in favor of the switch	
OTC switch would increase utilization of NRT	Use of NRT showed a sustained 152% increase after the OTC switch. Increased use likely resulted in savings of lives and dollars
NRT can be used effectively by consumers in an OTC setting	In effectiveness studies, NRT was effective under OTC conditions (superior to placebo and equivalent to Rx NRT). A prospective population study confirmed OTC efficacy
Concerns about the switch	
Consumers might use NRT unsafely	OTC experience and studies have confirmed safe use
Unsupervised consumer use of OTC NRT might increase persistent use and addiction	Rates of persistent use decreased following the OTC switch, and transfer of tobacco dependence to NRT is rare
With open access, teens or non-smokers might use/abuse NRT	Use by teens or non-smokers has been very rare
OTC status would diminish physician involvement in smoking cessation and NRT	Physician involvement was low prior to the OTC switch, and has increased post-switch. Physicians frequently recommend OTC NRT to patients
With OTC status, smokers would lose access to effective behavioral treatment	Utilization of behavioral treatment was low prior to the OTC switch. OTC NRT products have disseminated effective web-based tailored behavioral programs



Thank You

We are dedicated to improving the quality of human life by enabling people to do more, feel better and live longer

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