



EUROPE

CHILDREN AND FAMILIES
EDUCATION AND THE ARTS
ENERGY AND ENVIRONMENT
HEALTH AND HEALTH CARE
INFRASTRUCTURE AND
TRANSPORTATION
INTERNATIONAL AFFAIRS
LAW AND BUSINESS
NATIONAL SECURITY
POPULATION AND AGING
PUBLIC SAFETY
SCIENCE AND TECHNOLOGY
TERRORISM AND
HOMELAND SECURITY

The RAND Corporation is a nonprofit institution that helps improve policy and decisionmaking through research and analysis.

This electronic document was made available from www.rand.org as a public service of the RAND Corporation.

Skip all front matter: [Jump to Page 1](#) ▼

Support RAND

[Browse Reports & Bookstore](#)

[Make a charitable contribution](#)

For More Information

Visit RAND at www.rand.org

Explore [RAND Europe](#)

View [document details](#)

Limited Electronic Distribution Rights

This document and trademark(s) contained herein are protected by law as indicated in a notice appearing later in this work. This electronic representation of RAND intellectual property is provided for non-commercial use only. Unauthorized posting of RAND electronic documents to a non-RAND Web site is prohibited. RAND electronic documents are protected under copyright law. Permission is required from RAND to reproduce, or reuse in another form, any of our research documents for commercial use. For information on reprint and linking permissions, please see [RAND Permissions](#).

This report is part of the RAND Corporation research report series. RAND reports present research findings and objective analysis that address the challenges facing the public and private sectors. All RAND reports undergo rigorous peer review to ensure high standards for research quality and objectivity.

Availability, accessibility, usage and regulatory environment for novel and emerging tobacco, nicotine or related products

Ellen Nolte, Annalijn Conklin, Laura Brereton, Claire Celia,
Simo Goshev, Flavia Tsang, Clémence Pasmans

Availability, accessibility, usage and regulatory environment for novel and emerging tobacco, nicotine or related products

Ellen Nolte, Annalijn Conklin, Laura Brereton, Claire Celia,
Simo Goshev, Flavia Tsang, Clémence Pasmans

December 2012

The research described in this report was prepared for the Executive Agency for Health and Consumers (EAHC).

RAND Europe is an independent, not-for-profit policy research organisation that aims to improve policy and decisionmaking in the public interest through research and analysis. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

RAND® is a registered trademark.

© European Union, 2013

Reproduction is authorised provided the source is acknowledged.

Published 2013 by the RAND Corporation
1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
Westbrook Centre, Milton Road, Cambridge CB4 1YG, United Kingdom
RAND URL: <http://www.rand.org>
RAND Europe URL: <http://www.rand.org/randeurope>
To order RAND documents or to obtain additional information, contact
Distribution Services: Telephone: (310) 451-7002;
Fax: (310) 451-6915; Email: order@rand.org

Preface

The European Commission Health and Consumer Directorate-General (DG SANCO) commissioned RAND Europe, by way of the Executive Agency for Health and Consumers (EAHC), in the framework of the Health Programme (N° SC 2010 6306), to examine the availability, accessibility, usage and regulatory environment for novel and emerging tobacco, nicotine and related products in European Union Member States. Drawing on a range of methodological approaches involving systematic evidence review, key informant interviews with representatives from industry, including retailers, and a survey of stakeholders at national governmental and non-governmental agencies, this report serves to inform further a possible revision of the Tobacco Products Directive 2001/37/EC. The report also provides an overview of the evidence and basis for current tobacco and related products regulation that may be of interest to a wider audience interested in tobacco control policies. The research presented in this report reflects the evidence available at September 2011.

RAND Europe's work is objective, multidisciplinary and based on the core value of quality. All our products are peer reviewed before final dissemination as part of our quality assurance procedures. For more information about RAND's quality standards please see <http://www.rand.org/standards>.

For more information about this document or RAND Europe, please contact:

Dr Ellen Nolte

RAND Europe
Westbrook Centre
Milton Road
Cambridge CB4 1YG
United Kingdom
Tel. +44 (1223) 353 329
enolte@rand.org

Contents

| | |
|---|-----------|
| Preface..... | iii |
| Contents..... | v |
| List of figures..... | vii |
| List of tables | ix |
| Abbreviations and acronyms | xi |
| Acknowledgements..... | xii |
| CHAPTER 1 Introduction..... | 1 |
| Aims and objectives | 2 |
| CHAPTER 2 Our approach..... | 5 |
| 2.1 Evidence review..... | 5 |
| 2.1.1 Developing a typology of novel and emerging tobacco, nicotine or related products..... | 5 |
| 2.1.2 Evidence review stage II..... | 11 |
| 2.2 Key informant interviews..... | 13 |
| 2.3 Stakeholder survey on novel and emerging tobacco, nicotine or related products | 14 |
| CHAPTER 3 Availability, accessibility and use of novel and emerging tobacco, nicotine or related products: evidence review | 17 |
| 3.1 Combusted tobacco-free products | 18 |
| 3.1.1 Herbal cigarettes | 18 |
| 3.1.2 Non-tobacco preparations used in waterpipes | 18 |
| 3.1.3 Availability, accessibility and usage of combusted tobacco-free products..... | 19 |
| 3.2 Smokeless tobacco products..... | 19 |
| 3.2.1 Dissolvable tobacco products | 20 |
| 3.2.2 Tooth powders..... | 20 |
| 3.2.3 Tobacco pastes..... | 20 |
| 3.2.4 Availability, accessibility and usage of smokeless tobacco products..... | 20 |
| 3.3 Smokeless nicotine products..... | 21 |
| 3.3.1 Inhaled smokeless nicotine products | 21 |

| | | |
|-------------------|--|-----------|
| 3.3.2 | Availability, accessibility and usage of inhaled smokeless nicotine products..... | 22 |
| 3.3.3 | Orally consumed smokeless nicotine products: nicotine lollipops, mints, lozenges, wafers and drinks..... | 23 |
| 3.3.4 | Availability, accessibility and usage of orally consumed nicotine products..... | 24 |
| 3.3.5 | Dermally applied smokeless nicotine products: nicotine toothpaste, toothpick, creams, balms and condoms..... | 24 |
| 3.3.6 | Availability, accessibility and usage of dermally applied nicotine products..... | 25 |
| CHAPTER 4 | Marketing of novel and emerging tobacco, nicotine or related products: key informant interviews | 27 |
| 4.1 | Overview | 27 |
| 4.2 | Marketing of specific products: combusted tobacco-free products..... | 29 |
| 4.3 | Marketing of specific products: smokeless tobacco products..... | 29 |
| 4.4 | Marketing of specific products: smokeless nicotine products..... | 30 |
| CHAPTER 5 | Availability, accessibility and use of novel and emerging tobacco, nicotine or related products: stakeholder survey | 35 |
| 5.1 | Background information on respondents..... | 35 |
| 5.2 | Availability of novel and emerging tobacco, nicotine or related products per country products in EU Member States..... | 37 |
| 5.3 | Tobacco, nicotine or related products classified as NRT in EU Member States..... | 42 |
| 5.4 | Regulation of novel and emerging tobacco, nicotine or related products in EU Member States | 43 |
| 5.4.1 | Product availability by regulatory status..... | 43 |
| 5.4.2 | Restrictions on advertising and the sale of novel and emerging tobacco, nicotine or related products in EU Member States | 48 |
| 5.4.3 | Age restrictions on the purchase of novel and emerging tobacco, nicotine or related products in EU Member States | 53 |
| 5.5 | Summary..... | 54 |
| CHAPTER 6 | Conclusions | 56 |
| REFERENCES | 59 | |
| | Reference list..... | 61 |
| APPENDICES | 67 | |
| | Appendix A Evidence review stage I..... | 68 |
| | Appendix B Key informant interview topic guide..... | 71 |
| | Appendix C Abbreviated survey addressed to medicines agencies | 72 |
| | Appendix D Regulation of novel tobacco and nicotine products by type of regulation | 74 |

List of figures

| | |
|---|----|
| Figure 2.1 Product category: combusted products..... | 8 |
| Figure 2.2 Product category: smokeless tobacco products..... | 9 |
| Figure 2.3 Product category: smokeless nicotine products..... | 10 |

List of tables

| | |
|---|----|
| Table 2.1 Overview of the Products Compendium | 11 |
| Table 2.2 Overview of search strategy for published literature on the availability, accessibility and use of novel tobacco, nicotine or related products..... | 12 |
| Table 5.1 Number of respondents by country..... | 36 |
| Table 5.2 Respondents by type of organisation | 37 |
| Table 5.3 Novel and emerging tobacco, nicotine or related products availability by EU Member State | 38 |
| Table 5.4 Novel and emerging tobacco, nicotine or related products by location of purchase in EU Member States | 40 |
| Table 5.5 Novel tobacco, nicotine or related products by NRT classification in EU Member States | 42 |
| Table 5.6 Novel tobacco, nicotine or related products by regulatory status in EU Member States | 44 |
| Table 5.7 Novel nicotine and tobacco products by the type of national regulation under which they are regulated..... | 46 |
| Table 5.8 Restrictions on advertising imposed on novel tobacco, nicotine or related products in EU Member States | 48 |
| Table 5.9 Regulatory measures aimed at controlling the sale of novel tobacco, nicotine or related products available for purchase in EU Member States | 49 |
| Table 5.10 Labelling requirements for the sale of novel tobacco, nicotine or related products in EU Member States | 51 |
| Table 5.11 Age restrictions on the purchase of novel tobacco, nicotine or related products in EU Member States | 53 |
| Table A.1 Search terms and records identified, PubMed database | 68 |
| Table A.2 Search terms and records identified, targeted journals and newsletters | 69 |
| Table A.3 Search terms and records identified, (non-)governmental organisations | 69 |
| Table A.4 Sources of trade information on tobacco and nicotine products | 70 |

Abbreviations and acronyms

| | |
|----------|--|
| DG SANCO | European Commission Directorate-General for Health and Consumers |
| EAHC | European Executive Agency for Health and Consumers |
| EC | European Commission |
| ENDS | Electronic nicotine delivery systems; electronic cigarettes |
| ESTOC | European Smokeless Tobacco Council |
| EU | European Union |
| FCTC | Framework Convention on Tobacco Control |
| FD&C | Food, Drug, and Cosmetic Act |
| FDA | US Food and Drug Administration |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| NRT | Nicotine replacement therapy |
| PACT | 2010 Prevent All Cigarette Trafficking Act |
| SFI | Smokefree Innotec |
| TECC | The Electronic Cigarette Company |
| TSCC | The Smokeless Cigarette Company |
| TSNA | Tobacco specific nitrosamine |
| UK | United Kingdom |
| WHO | World Health Organization |

Acknowledgements

The research presented in this report was funded by the European Commission Directorate-General for Health and Consumers by way of the Executive Agency for Health and Consumers (EAHC), in the framework of the Health Programme (N° SC 2010 6306). The research presented in this report reflects the evidence available at September 2011.

We gratefully acknowledge the very helpful and insightful comments and suggestions provided by Anna Gilmore, Silvy Peters, Ann McNeill and Tom Ling on earlier drafts of this report. We are also very grateful to the European Commission Directorate-General for Health and Consumers and the EAHC for their support in discussing and further developing this report.

The views expressed in this report are those of the authors alone and do not necessarily represent those of the European Commission Directorate-General for Health and Consumers or the EAHC. The authors are fully responsible for any errors.

Any references made in this document to third-party trade names and trademarks are for illustrative purposes.

There has been considerable progress across the European Union (EU) towards reducing the prevalence of smoking and exposure to second-hand smoke.¹ For example, over one-third of countries in the EU have adopted smoke-free regulations during the past decade,² and a series of tobacco control regulations and recommendations have also been initiated at the EU level.³ At the international level, 26 out of 27 EU Member States, along with the European Commission, had ratified the World Health Organization Framework Convention on Tobacco Control (FCTC) by January 2011,⁴ thereby committing to implementing a wide range of tobacco control measures foreseen by the framework convention.

One of the core instruments developed at the EU level is the Tobacco Products Directive 2001/37/EC, which regulates the composition and labelling of tobacco products. The Directive covers tobacco products “for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco”.⁵ Adopted in 2001, the Directive covers all tobacco products that were on the market at that time. However, in recent years there has been a diversification of tobacco, nicotine and other novel and niche products in use, with traditional products such as waterpipes (eg shisha or hooka) appearing to become more popular, especially among young people, while new products such as electronic cigarettes or dissolvable smokeless tobacco⁶ and novel products that imitate cigarettes without tobacco or nicotine (eg herbal cigarettes such as ‘Farmer’s Honey Blend mixture’^a) are also appearing on the market.

Many of these new products are marketed as ‘less harmful’ than cigarettes, or suggested as an aid to quitting smoking cigarettes. Yet, the health impacts of novel products remain inadequately understood. Available evidence indicates that consumers do not have good knowledge about the harmfulness of these new products and underestimate the health risks of their use.^{3 7} There is also concern that novel tobacco, nicotine or related products may act as a ‘gateway’ to (rather than from) nicotine addiction, which may result in cigarette smoking or else might act as an alternative means for young people who would not take up smoking otherwise, although the evidence is mixed.⁸

While there is a need to better understand the direct and indirect health impacts of novel and emerging tobacco, nicotine or related products⁹ it is also important to better understand the extent to which these products are available on European markets, and their accessibility and use. Furthermore, our earlier work showed how Member States vary

^a Farmer’s Honey Blend is an aromatic mixture of marshmallow leaves, red clover flowers and rose petals.

with regard to the degree to which products such as electronic and herbal cigarettes are regulated,³ although the overall regulatory framework for novel and emerging tobacco, nicotine and related products across the EU is not well documented. Such products might be covered by extending the scope of the Tobacco Products Directive; however, other legislation on pharmaceuticals, general food and product safety might also apply. There is therefore a need to examine the present regulatory framework to identify regulatory gaps in EU legislation and the options available to amend them in order to serve public health and internal market objectives.

Aims and objectives

This report seeks to further inform the possible revision of the Tobacco Products Directive 2001/37/EC through:

- providing an overview of the availability and accessibility of novel and emerging tobacco, nicotine or related products and present regulatory environment of these products
- analysing the gaps in EU legislation and present possible regulatory options to address such gaps.

To inform the overview of the availability and accessibility of novel tobacco and nicotine products, we sought to:

- define a compendium of novel and emerging tobacco, nicotine or related products available on the EU market, including a classification and description of key features of each product
- collect information on the availability, accessibility and use of novel and emerging tobacco, nicotine or related products as well as on the marketing of these products in the EU market
- collect and analyse information on existing Member State legislation that regulates these products.

To analyse the gaps in EU legislation, we:

- identify gaps in EU legislation by identifying those novel and emerging tobacco, nicotine or related products that do not, or only partly, fall either under tobacco, food or pharmaceutical legislation
- outline possible regulatory options to address the regulatory gaps identified for such novel and emerging tobacco, nicotine or related products, aiming at a high level of public health protection in the internal market.

This report is structured as follows: Chapter 2 sets out with a description of the methodological approach we employed in this study. It also describes the development of a typology of products which guided the data collection on novel and emerging tobacco, nicotine or related products to be addressed in this work. Chapter 3 provides an overview of the findings of the evidence review, which should be read in conjunction with the appended electronic products database (the Products Compendium). Chapter 4 reports on the marketing of novel and emerging tobacco, nicotine or related products and Chapter 5 provides an overview of the findings of a survey of key informants in the 27 Member States

on availability and legislation of these products. Chapter 6 summarises the key observations of the entire study and provides tentative conclusions on the basis of the evidence gathered, with suggestions for advancing the wider evidence base and regulatory certainty.

2.1 **Evidence review**

We carried out a two-staged review of the evidence. A first stage aimed to identify the range of novel and emerging tobacco, nicotine or related products that are or may be available within European markets. This initial search informed the development of a typology of products, which guided the second stage of the evidence review. We describe the two stages in turn.

2.1.1 **Developing a typology of novel and emerging tobacco, nicotine or related products**

The first stage of the evidence review involved a comprehensive search of a range of information sources, using an iterative approach. This stage took a deliberately broad approach to enable (i) identification of the range of products to be examined in more detail and (ii) informing the development of a typology of novel and emerging tobacco, nicotine or related products.

Databases and information sources considered for the comprehensive search of products for the typology stage of our review were:

- bibliographical databases
- selected tobacco journals and newsletters
- governmental, inter- and non-governmental organisations
- industry sources
- other sources.

Inclusion and exclusion criteria

We used a broad range of search terms and included all records that mentioned a novel tobacco and/or nicotine product. We defined 'novel' tobacco, nicotine or related products as all products that are not considered as medicinal products used for smoking cessation, such as nicotine patches, nicotine gums, nicotine inhalers/nasal nicotine spray and non-nicotine medications/therapies. We further considered the term 'novel' not to be limited to new products on the market, but to include traditional products that have been present on the market for some time and the use of which is increasing (eg waterpipe, herbal cigarettes). We excluded *snus* because this product is already regulated under the Tobacco Products Directive 2001/37/EC.

Depending on the information source, a ‘record’ was defined as referring to a peer-reviewed (empirical) study, review and (non-)governmental report, news/press release, manufacturer product description, marketing report, database and so on. We excluded records that focused on the health impacts of new products, their use in harm reduction and/or smoking cessation, and/or the environmental impacts of new products. The distinction between novel nicotine products for use other than medicinal (as a smoking cessation aid) was in some cases difficult to assess; we have therefore adopted a broad approach in the first instance and also included those products that may be marketed as smoking cessation aids regardless of their classification as pharmaceuticals by relevant national authorities.

Where appropriate and relevant, we used search terms in languages other than English to explore the extent to which employing solely English language search terms would restrict the comprehensiveness of searches. To test for the potential bias introduced, we used terms in Bulgarian (‘тревни цигари’ [herbal cigarettes], ‘тютюневи изделия’ [tobacco paste], ‘тютюнева паста’ and ‘тютюнева вода’ [tobacco water], ‘никотинова вода’ [nicotine water], ‘електронни цигари’ [electronic cigarettes], ‘тютюн за наргиле’ [hookah], ‘тютюнева напитка’ [tobacco drink]), French (eg ‘cigarettes sans tabac ni nicotine or cigarettes plantes’ [herbal cigarettes], ‘cigarettes électroniques’ [electronic cigarettes], ‘eau à la nicotine’ [nicotine water], ‘cure dents à la nicotine’ [nicotine toothpick], ‘lozenges à la nicotine or pastilles de nicotine’ [nicotine lozenges]) and German (eg ‘Nelkenzigaretten’ [clove cigarettes], ‘Nikotindrink, getränk or trunk’ [nicotine drink], ‘elektronische Zigarette’ [electronic cigarette], ‘rauchfreies Tabakproduct’ [smoke-free tobacco]). However, while these searches identified some original language web posts, products and companies, these were usually related to English language products, for example, a Bulgarian online retailer for electronic cigarettes¹⁰ or a French equivalent,^{11 12} or would lead to English language websites.^{13 14} While arguably having considered only a subset of the languages spoken within the EU, we feel confident that we have captured the range of products that may be available on the market. Indeed, as Chapter 4 illustrates, the preferred marketing outlet for many of the novel and niche tobacco, nicotine or related products is through the internet and is therefore likely to have been captured by our searches. A detailed overview of the searches undertaken in this first stage of the evidence review is given in Appendix A.

Building on the findings of this first stage, we developed a draft typology of tobacco, nicotine or related products, which, following review by DG SANCO, was further refined. The typology principally distinguishes three types of product:

- combusted products
- non-combusted tobacco products
- non-combusted nicotine products.

These types of product can be further distinguished into sub-types, which are illustrated for each product category in Figure 2.1, 2.2 and Figure 2.3. Non-combusted tobacco and nicotine products were further classified according to the main point or passage of entry as nasal, oral or dermal. However, in selected cases this classification was not clear-cut. Nicotine toothpaste provides an example of a product that enters the human body via both

oral and dermal passages. We here classify this product as ‘dermal’ while accepting that other classifications might consider the main mode of passage as ‘oral’. The product typology depicted below comprises all products identified from our preliminary review of the available evidence. It should be noted that several of the products listed are already covered by the Tobacco Products Directive 2001/37/EC; these include, in addition to *snus* mentioned above, tobacco products used for waterpipes, chewing tobacco and snuff. These products were therefore excluded from further detailed review as presented in Chapter 3 and the online survey of Member State legislation regulating novel and emerging tobacco, nicotine or related products presented in Chapter 5. However, we should note, following discussions with the Commission, that the Products Compendium described in the next section has retained basic information on the availability, accessibility and usage for this subset of smokeless tobacco products.

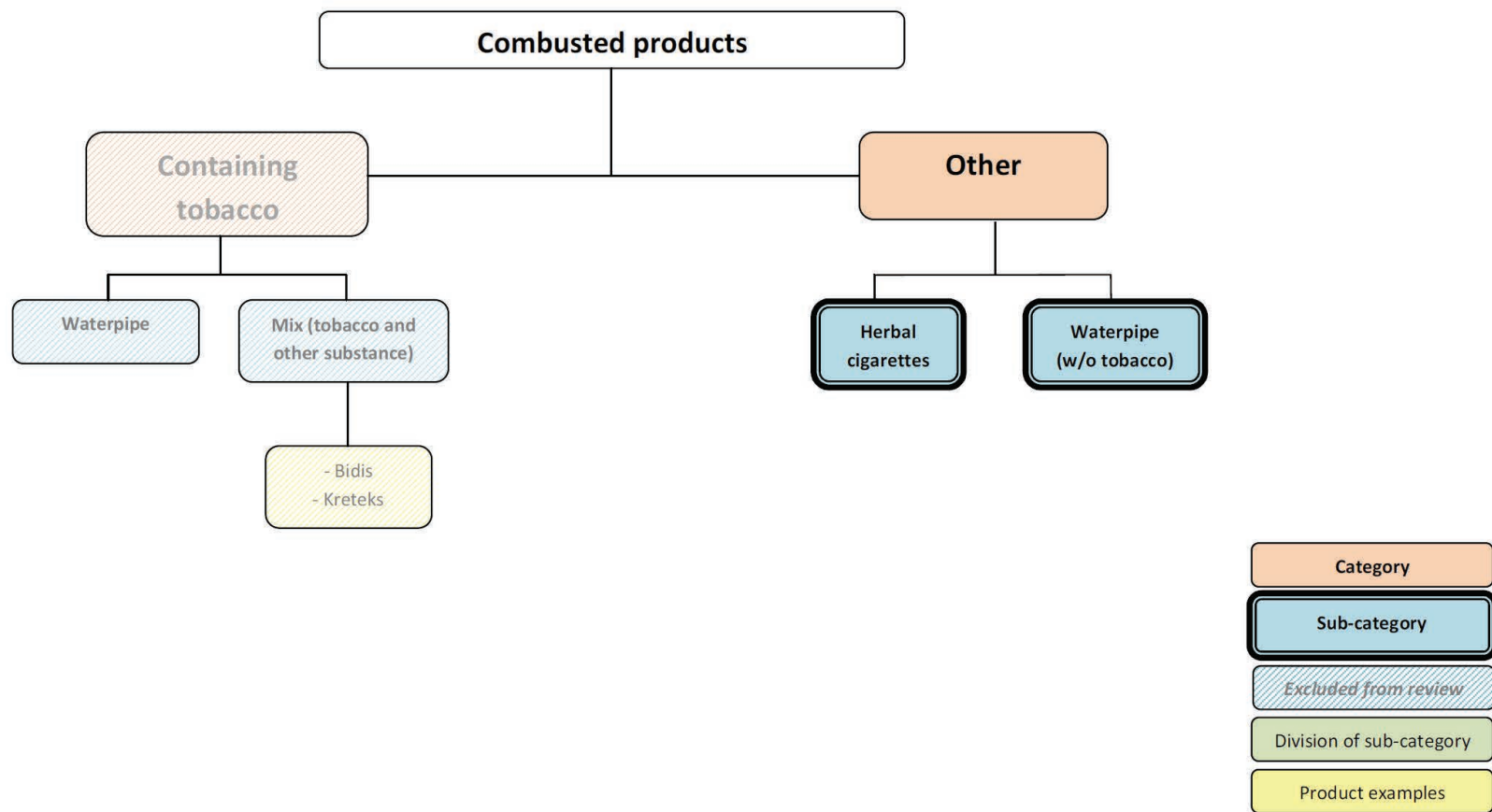


Figure 2.1 Product category: combusted products

SOURCE: authors

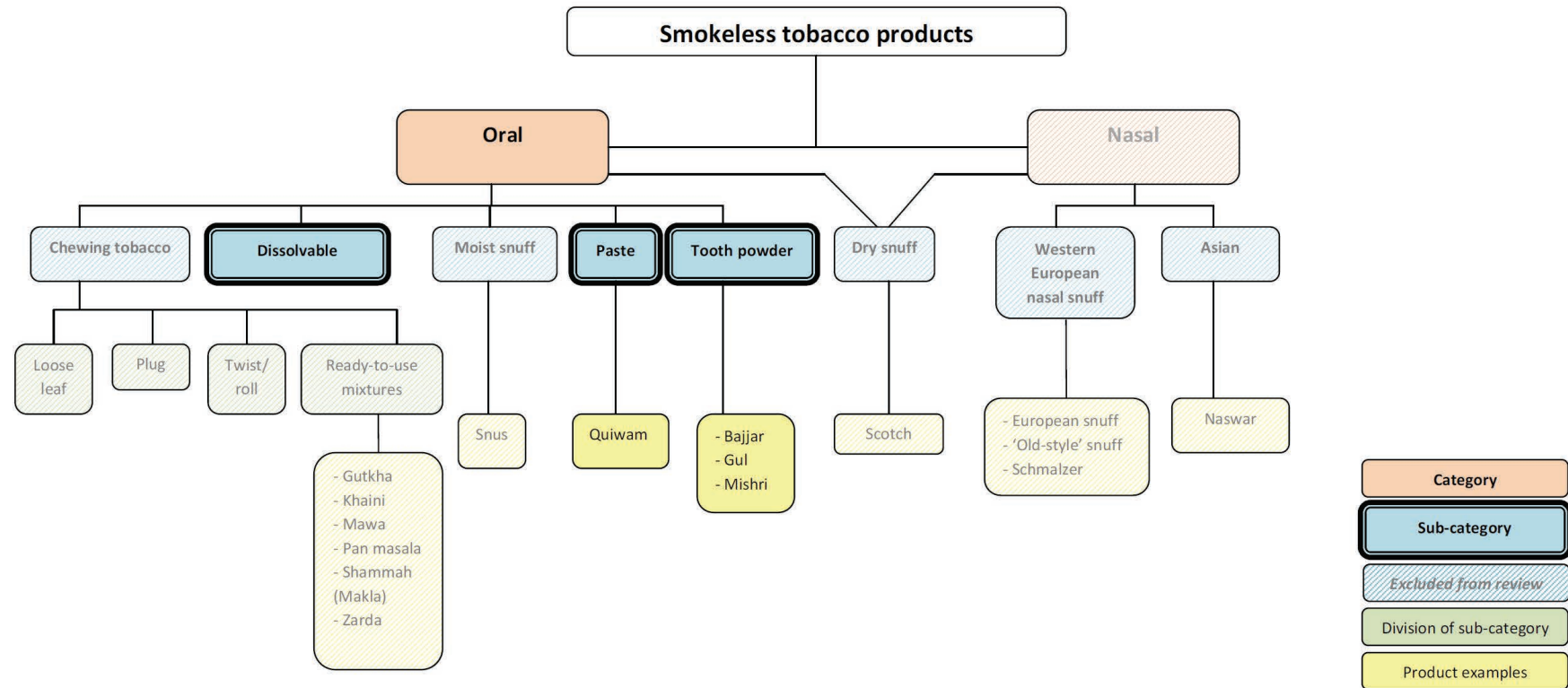


Figure 2.2 Product category: smokeless tobacco products

SOURCE: adapted from CORRESTA (2010)¹⁵

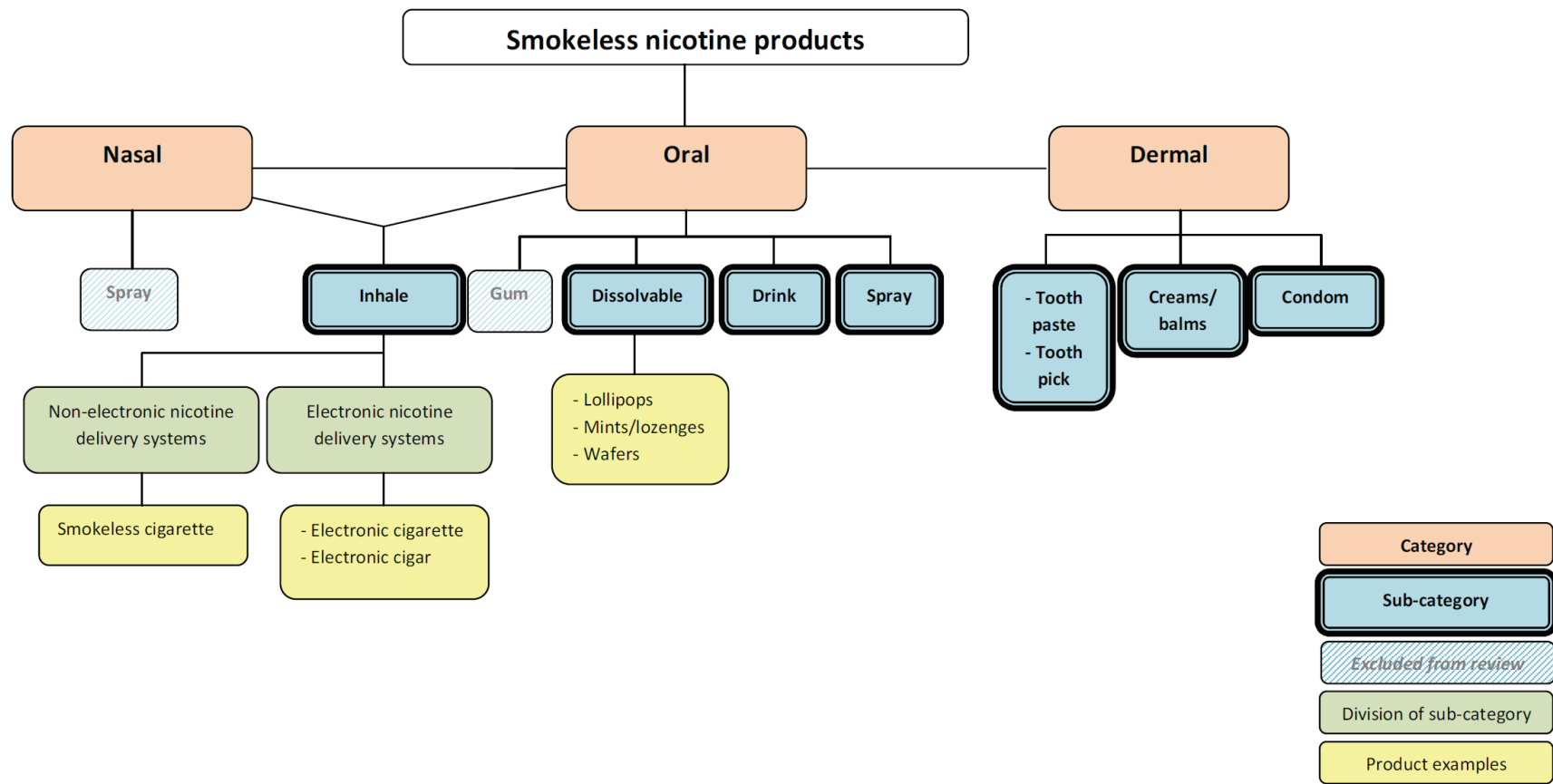


Figure 2.3 Product category: smokeless nicotine products

SOURCE: authors

Electronic products database (Products Compendium)

Based on the information collected within the first stage of the evidence review, we developed an electronic products database (the Products Compendium), which takes the form of a pivot table created within Microsoft® Excel. The Products Compendium serves as a resource characterising each identified novel and emerging tobacco and nicotine product included in our review, as described in Figure 2.1, 2.2 and Figure 2.3 by their key features. It includes information on the availability, accessibility and use of each product and its marketing, where available, as well as information obtained through the online key stakeholder survey as described below (in Section 2.3). Table 2.1 provides an overview of the types of data and information collected by the Products Compendium. The Compendium is available as an appended Excel file.

Table 2.1 Overview of the Products Compendium

| | |
|--|---|
| Product name (and other names) | |
| Brand names (incl. manufacturer if available) | |
| Region | |
| Country | |
| Product characteristics | <ul style="list-style-type: none">• Combusted (Y/N)• Containing tobacco (Y/N)• Containing nicotine (Y/N)• Point/passage of entry (nasal, oral or dermal)• Mode(s) of use (eg smoked, chewed, sniffed, swallowed, etc)• Components and characteristics (including method of production, eg fermented or otherwise)• Quantity of ingredients• Classification (eg food, pharmaceutical, etc) |
| Use and availability | <ul style="list-style-type: none">• Prevalence of use (by population group where possible)• Availability/market share• Purchasable on the internet?• Pricing |
| Marketing | <ul style="list-style-type: none">• Methods of marketing• Target population/group• Product image |
| Regulation | <ul style="list-style-type: none">• Type of legislation• Partial or full legislation |
| Sources | |
| Comments/remarks | |
| Classified as nicotine replacement therapy (NRT) | <ul style="list-style-type: none">• Y/N |

SOURCE: Based on survey results from Member State medicines agencies

2.1.2 Evidence review stage II

The second stage of the evidence review aimed at systematically collecting information on the availability, accessibility and usage for each identified product within the three product categories combusted products, smokeless tobacco products and smokeless nicotine products (Figure 2.1, 2.2 and Figure 2.3) to further populate the electronic Products

Compendium described in Section 2.1.1. We carried out a comprehensive search of the published literature using the two biomedical databases PubMed and Embase. We used the following search terms, on their own or in combination: ‘usage’, ‘availab*’, ‘incidence’, ‘prevalence’, ‘uptake’, ‘access*’ and ‘utili*’ combined with the specific product category under review. Table 2.2 provides an overview of the search strategy employed for each product category.

Table 2.2 Overview of search strategy for published literature on the availability, accessibility and use of novel tobacco, nicotine or related products

| Product type | Category, sub-category | Product | Search term combinations ('/' indicates 'or') |
|-----------------------------|------------------------|--|---|
| Smokeless tobacco products | Oral | Dissolvable tobacco (eg tablet, pellet, stick, strip, water) | Smokeless tobacco; dissolvable/soluble/tablet*/pellet*/stick*/strip*/water/drink*/cocktail*; Usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | | Tobacco paste | Smokeless tobacco; tooth paste/tooth/paste/creamy snuff/ipco/quiwam/dentobac/tona/ganesh; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | | Tobacco tooth powder | Smokeless tobacco; tooth powder/tooth/bajjar/bjagar/gul/gadakhu/mishri/mshri; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| Smokeless nicotine products | Oral/nasal, inhaled | Electronic nicotine delivery systems | ELectronic cigarette/greensmoking/electronically heated cigarette/vapor cigarette/electronic nicotine delivery system/smokeless cigarette; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | Oral, dissolvable | Dissolvable nicotine (eg lollipops, mints, lozenges, wafers) | Nicotine; dissolvable/soluble; lollipop/NicoStop Lollipop/Nicopop/likatine/wafer*/NicoVar inc/lozenge*/mint*/niquitin/nicotinell; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | Oral, swallowed | Nicotine drink | Nicotine; drink/SJ xxx-Energy Nicofix/Nic Lite; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | Dermal | Nicotine toothpaste or toothpick | Nicotine toothpaste; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | | Nicotine cream or balm | Nicotine cream/balm; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | | Nicotine condom | Nicotine condom; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| Combusted products | Tobacco-free | Herbal cigarettes | Herbal cigarette/honey rose/honeyblend/tobacco-free cigarette; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |
| | | Waterpipe | Waterpipe; tobacco-free/cannabi*/hemp/marijuana; usage/availab*/incidence/prevalence/uptake/access*/utili*/regulat* |

Inclusion and exclusion criteria

We included records that reported data on availability, accessibility, usage and regulation in the EU only. Records that examined or compared the health effects of products searched were excluded.

2.2 Key informant interviews

We conducted targeted interviews with key informants representing public relations departments of manufacturers and/or manufacturer associations of novel and emerging tobacco, nicotine or related products to supplement the information on marketing, sales and pricing arrangements identified in the evidence review.

We first conducted a scoping review of tobacco trade journals and magazines for ‘novel’ products and either mentions of marketing or actual advertisements. Publications considered for the review included print issues of *World Tobacco* (2009) and the *Tobacco Journal International* (2009–2010) (now merged into *World Tobacco*¹⁶), which were hand searched, as well as the online industry journals and magazines *Tobacco Journal International* (search terms: ‘novel’, ‘smokeless’ (section: ‘Products and trends’))¹⁷ and *Tobacco Reporter* (search terms: ‘novel’, ‘smokeless’).¹⁸

We further hand searched market research reports compiled by *Euromonitor International*, a leading international consumer market research company, identifying four relevant issues following a search for the ‘global tobacco’ industry files for ‘marketing’ and ‘new products’:

- ‘Global Tobacco: Survival Strategies for a Savage Market’ (Nov 2008)¹⁹
- ‘Global Tobacco: New Product Developments – Regional and Country Overview’ (Sep 2009)²⁰
- ‘Global Tobacco: New Product Developments – Creativity in Adversity’ (Dec 2009)²¹
- ‘Smokeless Tobacco – Is it the Future of the Industry?’ (Apr 2010).²²

In addition, we carried out web-based searches that involved reviewing manufacturer and retailer websites and press releases, general Google searches for media and press mentions of chosen products, and browsing online groups and clubs of novel product users.

In a second stage, we aimed to acquire a more in-depth understanding of the marketing and targeted customer demographic for a subset of products from each of our primary product categories (combusted products, smokeless tobacco products and smokeless nicotine products) through undertaking key informant interviews. Products considered for in-depth exploration were: herbal cigarettes, dissolvable tobacco and electronic cigarettes, therefore covering sub-types in each of the three typologies described in Figure 2.1, 2.2 and Figure 2.3.

Building on the information collected in the scoping review described above, we identified six retailers or producers of the products to be reviewed. We identified the names of a marketing or director-level executive at each company who were invited, by email, to participate in a confidential interview. The interview used a topic guide, covering the market for the product in question in Europe, and the relevant company’s approach to marketing; the interview topic guide is presented in Appendix B. Interviews were undertaken via telephone, lasting on average 20 minutes. Notes were taken during interviews as they were not audio recorded. The notes were then analysed thematically to explore key issues and ideas relevant to methods of marketing, target consumer demographic, product image, and so on.

Of the six companies contacted twice (one initial invitation and one follow-up reminder), four responded and were willing to be interviewed. Two represented European electronic cigarette manufacturers or retailers, one represented a producer of a smokeless cigarette alternative, and one represented a leading producer of smokeless tobacco products in the US. Executives at a nicotine drink producer and a producer of herbal cigarettes did not respond following repeated telephone and email follow-up and therefore had to be excluded from further consideration in this report.

2.3 **Stakeholder survey on novel and emerging tobacco, nicotine or related products**

We carried out an online stakeholder survey in the 27 Member States of the EU. The aim of the online survey was to collect additional information on the availability, accessibility and use as well as the regulation of novel and emerging tobacco, nicotine or related products as described in Section 2.1.

The survey was designed by the research team and reviewed by external experts and DG SANCO. We piloted the online survey in-house with five researchers (involving researchers from the project team and researchers outside the team) to ensure that the wording of questions was appropriate and the instrument usable.

Data collection using the survey was undertaken between 18 April 2011 and 22 June 2011, following a multiple-staged approach. In a first stage, respondents with documented or likely expertise in the field were identified among departments or ministries of health, regulatory agencies (including medicines agencies, see below), public health agencies and non-governmental organisations through systematic searches of relevant websites and sources. The research team aimed to identify at least three respondents per country to maximise the likelihood of obtaining a response from all Member States. For some Member States, potential respondents were easier to identify. For example, we identified 15 contacts for the UK and seven for Spain but only two for Estonia and Italy, respectively. In doing so, we identified a total of 123 individuals or organisations across the 27 Member States who were invited, by email, to participate in the survey. Of these, two email addresses were not valid.

In order to maximise response rates, we launched three sets of reminders to complete the survey at different stages during data collection, approximately 2.5 weeks following, respectively, the initial invitation or the reminder, targeting those Member States where no response or only one response had been received. Where named contacts were available, we used personalised invitations so as to increase the likelihood of obtaining a response. Where appropriate, we used native language invitation letters for those countries where no response had been received, for example in the French language to obtain information from French speaking Member States (France and Belgium). In addition, following discussions with DG SANCO, an additional round was launched, targeting ministries of trade or business in all 27 Member States, coinciding with the third reminder for the initial sample.

As indicated in Section 2.1.1, the distinction of novel nicotine products for use other than medicinal, as smoking cessation aids, was in some cases difficult to assess from the

published and grey literature searched, and we therefore aimed to obtain this information through the online survey by also targeting national medicines agencies. To ensure collection of as robust information as possible, we included a separate round of an abbreviated version of the online survey, covering nicotine products only, and targeting those agencies in Member States that had not responded to the full survey (Appendix C). Any additional responses obtained from this round were incorporated into the survey data for further analysis, as presented in Chapter 5.

Data were principally analysed using descriptive statistics. Where there was more than one response from a given Member State, and where these conflicted, regarding for example the regulatory status of a given product, we developed an algorithm to reconcile these differences. Details of this approach are given in Chapter 5.

CHAPTER 3 **Availability, accessibility and use of novel and emerging tobacco, nicotine or related products: evidence review**

This chapter reports on the findings of the evidence review of the availability, accessibility and use of novel and emerging tobacco, nicotine or related products. At the outset it is important to note that, because of the novel or emerging nature of the products reviewed here, published information and data on these products remain somewhat patchy. Indeed, the review had to rely to a considerable extent on information retrieved from online sources. These included manufacturer or retailer websites as well as newsletters and information by tobacco control NGOs and agencies, and were complemented by information extracted from industry trade journals and magazines, manufacturer or retailer websites, and press releases (see Chapter 4). Because of the nature of these sources, the level of detail of information extracted varies widely as does its quality; also, it is difficult to assess the degree to which we have been able to capture the full extent of information presented in online sources in particular.

Data from market research companies is available for purchase; however, these data tend to focus exclusively on the subset of tobacco products not covered in this research, namely chewing tobacco and snuff. These account for the largest proportion of smokeless tobacco products (see also Chapter 4).²² Box 3.1 presents a brief overview of the type of data that are available commercially.

Box 3.1 Market research on smokeless tobacco products

Euromonitor International offers detailed reports on smokeless tobacco products for a range of EU countries (Czech Republic, Denmark, Estonia, Germany, Latvia, Lithuania, Romania, Slovak Republic, Slovenia and Sweden), which report, to varying degrees, on the market size and share, brand share, distribution and pricing for two types of smokeless tobacco products: chewing tobacco (Asian-style, US-style, other) and snuff (moist snuff [US-style, 'dip']; Swedish-style *snus*; Asian-style creamy snuff); dry snuff and hard snuff). Each report is available for purchase at £600 per report. It should be noted that these reports only cover ten out of 27 EU Member States.²³ Importantly, given that the emphasis of the present report is on describing the availability, accessibility, usage and regulatory framework of products not currently covered by the Tobacco Products Directive, we did not purchase these data for analysis in this research.

In contrast, we were unable to identify market research data on the products reviewed here. While this lack of commercially available industry data might perhaps not be surprising in relation to some of the niche products presented below, such as herbal cigarettes, one might have expected more systematic data on products such as nicotine delivery systems, for example electronic cigarettes, to be available given their increasing popularity as described below.²⁴ However, as described in Chapter 4, at the time of writing this report the nature and size of the market is not well understood, and there is a lack of reliable information that would enable capturing the market for these products in detail.

The systematic search of the two biomedical databases PubMed and Embase, aimed at capturing the peer-reviewed literature on the availability, accessibility and usage of novel and emerging tobacco, nicotine or related products, identified a very small body of evidence only. Indeed, the only product category that was represented in the biomedical literature to a reasonable degree was that of smokeless tobacco products, typically chewing tobacco and snuff.^{8 25-27} It is important to note that this scarcity relates to studies of quantitative measures of availability, accessibility and use of these products; what is available tends to focus on assessing the health impacts and/or toxicology (carcinogenic components) of such products, consumer perception and/or awareness of novel products (and their risk), or the dual or 'polytobacco' use of novel products in combination with traditional products (eg cigarettes).

We here report on the (limited) documented, quantitative evidence on availability, accessibility and use of novel tobacco, nicotine or related products as identified from the sources described above only; this chapter does not report on information collected through the stakeholder survey, which is presented in Chapter 5. This overview should be read in conjunction with the appended electronic Products Compendium.

3.1 Combusted tobacco-free products

The two main combusted products considered in the review of combusted tobacco-free products are herbal cigarettes and non-tobacco preparations used in waterpipes (Section 2.1).

3.1.1 Herbal cigarettes

Herbal cigarettes are plant- or vegetable-based cigarettes that do not contain tobacco or, typically, nicotine, but may contain flavouring such as cherry, chocolate or marshmallow.²⁸ The product is often based on a mixture of, for example, ginseng, jasmine and catnip; or marshmallow leaves, red clover flowers and rose petals. Common brand names include: Farmer's Honeyblend Mixture, Knaster blends (hemp, red, cherry), Honeyrose De Luxe, Greengo Herb blend and Kratom black label.

3.1.2 Non-tobacco preparations used in waterpipes

There is a long tradition in many parts of the world, including the Eastern Mediterranean countries, the Middle East and parts of Asia²⁹, of smoking tobacco and other substances using waterpipes, also referred to as hookah or shisha pipes for example.^{30 31} With a variety of names such as argileh, hookah (or hooka), shisha or hubble-bubble, waterpipe smoking generally refers to tobacco use methods whereby smoke is passed through water before it is

inhaled.³¹ There are typically four main parts to a waterpipe: the bowl where the tobacco or other substance is burned; the base filled with water; the stem connecting the bowl to the base; and the hose with mouthpiece through which smoke is inhaled. While relevant information is difficult to ascertain, it is likely that non-tobacco preparations used in waterpipes include illicit substances.

3.1.3 **Availability, accessibility and usage of combusted tobacco-free products**

In reviewing the literature for both types of combusted tobacco-free products, we were not able to identify evidence of their availability, accessibility or usage in Europe. In general, studies that report on herbal cigarettes do so in terms of the health harms compared with tobacco cigarettes rather than its usage, accessibility or availability. Herbal cigarettes are principally available from health food stores (eg Holland & Barrett in the UK) or through online retailers (eg Everyone Does It).³² Honeyrose Farmers Honeyblend Smoking Mix is available from a range of online retailers, with the price ranging between around €5.60 (£4.99) for a 50g bag in the UK³² and €6.80 for a pack of 20 herbal cigarettes from an Italian online retailer.³³ Other websites where this particular product can be purchased indicate a price range of €2.88 (£2.50) up to €17.24 (£14.99). The UK-based brand Honeyrose provides a list of retailers across Europe and beyond³⁴ so the product is likely to be widely available. Given the ease of access through the internet, it is possible that these and related products are being used, although findings from previous work suggest that this type of product does not appear to be popular.³

Similarly, information on waterpipe smoking discussed this ‘novel’ product in general terms, comparing it to cigarette smoking, and both types of smoking involved (flavoured) tobacco use. The only identified peer-reviewed study that examined the use of non-tobacco preparations in waterpipes was excluded because it analysed acute effects of waterpipe tobacco smoking in comparison with a matched tobacco-free preparation.³⁵ We have previously reported on the use of waterpipes in the form of hookah, gaza, narghile, hubble-bubble and shisha.³ In brief, waterpipe smoking has become more common in Europe since the 1990s, particularly among young adults and college students,³⁶ although according to the 2010 Eurobarometer, regular waterpipe use remains fairly uncommon and waterpipes are typically only smoked occasionally.³⁷ Waterpipe smoking is often undertaken as a group activity and increased use has been linked to the perception that it has relatively safe health impacts.³⁶ We were not able to identify any reliable, publicly available information on the availability, accessibility and use of tobacco-free waterpipe smoking products, the use of which is likely to be under-reported.

3.2 **Smokeless tobacco products**

Smokeless tobacco is defined here as a type of consumable, non-combustible product containing tobacco. This type of product is primarily applied to oral or nasal surfaces and occasionally ingested. Following our typology, this section contains a description of known smokeless tobacco products, and where available information on manufacturers and common brands. Alternative names are presented in parentheses. As noted in Section 2.1, Swedish *snus*, chewing tobacco and snuff were excluded from our review, since these products are already covered by the Tobacco Products Directive.

3.2.1 Dissolvable tobacco products

Tobacco tablets (lozenges): Tobacco tablets are made of compressed, powdered tobacco and other flavour-giving ingredients such as mint and eucalyptus. They are smooth, about the size of a tic-tac or other small candy, and are left to melt in the mouth. In the US, Stonewall and Ariva tablets are produced by Star Scientific. There are 1.5mg of nicotine in Ariva and 4mg in Stonewall.³⁸

Tobacco sticks and strips: Sticks and strips made of finely ground flavoured tobacco. They are left to melt in the mouth.

Tobacco water (tuibur/hidakphu): Tobacco water is made by passing tobacco smoke through water. It is gargled and spat out by the user.

Tobacco-infused drinks: These drinks are made by adding fine tobacco powder to (or 'soaking' tobacco in) soft or alcoholic drinks. They are consumed as any other drink.

3.2.2 Tooth powders

Red tooth tobacco powder: This fine tobacco powder is mixed with herbs and flavouring. It is used as a teeth cleaning substance.

Bajjar: This fine, dry tobacco powder is often mixed with other ingredients and applied to gums and teeth. It is popular with women from Southeast Asia.

Gul (gadakhu): Machine-produced tobacco powder, molasses and other ingredients, sold in toothpaste-like tubes. It is applied to the gums and teeth and is often used as a cleaning substance.

Mishri: Tobacco powder manufactured by roasting powdered tobacco on a hot plate. It is applied to gums and teeth.

3.2.3 Tobacco pastes

Creamy snuff: Solution of powdered tobacco mixed with other ingredients (such as spearmint and menthol) into a paste. Common brands in Europe are IPCO and Dentobac. Tobacco pastes are often marketed as a dentifrice and sold in toothpaste-like tubes.^{39 40}

Quiwam: Liquid tobacco leaf extract and spices mixed to form a thick brown paste, which is chewed.

Khaini: Powdered tobacco and slaked lime paste are combined by users in their palm and formed into a ball. Areca nut is sometimes added. Common brand names are Nimantran and Wiz Three Stars.⁴¹

Other products

Tobacco-infused cocktail ingredients: Cocktail drink ingredients that have been smoked by tobacco (eg tobacco-smoked ice, tobacco-smoked fruits). They are consumed as any other edible ingredient.

3.2.4 Availability, accessibility and usage of smokeless tobacco products

As noted in the introduction to this chapter, studies of prevalence of use of smokeless tobacco products tend to focus on chewing tobacco and snuff.^{25 26 42-47} Of those reporting

on smokeless tobacco products more generally, Prignot et al. (2008) noted that smokeless tobacco is consumed by 400 million people worldwide, mainly in central and south India.⁴⁴ Similarly, McNeill et al. (2006) reported that while smokeless tobacco products account for more than a third of all tobacco consumed worldwide, they are much less common in the UK.⁴³ Thus, while we identified peer-reviewed studies that report on the prevalence of usage of smokeless tobacco products overall, we were unable to identify studies that specifically assessed the availability and use of smokeless tobacco products other than chewing tobacco and snuff.

3.3 **Smokeless nicotine products**

Smokeless nicotine products reviewed here include nasal nicotine spray, electronic cigarettes, dissolvable nicotine products, nicotine drinks, nicotine toothpaste, nicotine toothpick, nicotine creams or balms and nicotine condoms (see Section 2.1). Available information suggests that the most common smokeless nicotine products are nicotine delivery systems, frequently referred to as electronic cigarettes, although including a larger variety of product. At the outset it is important to note that available empirical research on the availability, accessibility, usage or regulation of smokeless nicotine products is fairly slim; Fagerström (2005) reported comparative numerical data for Europe on the uptake of smokeless nicotine products, but classified such products as ‘nicotine replacement’ without a definition.⁴⁸

3.3.1 **Inhaled smokeless nicotine products**

Smokeless nicotine products which can be inhaled are commonly referred to under the umbrella term electronic nicotine delivery systems (ENDS), encompassing product categories such as electronic cigarettes or e-cigarettes, and the electronically heated cigarettes system (EHCSS). More recent developments include non-electronic nicotine products, frequently referred to as smokeless cigarettes, although this term is also used for electronic cigarettes (see Box 3.2).

According to industry sources, electronic cigarettes involve a battery operated device consisting of a nicotine and propylene glycol cartridge and an atomiser to deliver nicotine to users through the resulting vapour, which comprises 80 percent water and glycerin.⁴⁹ It is explained that when a user sucks on the device, a sensor detects air flow and heats the liquid in the (one- or two-step) cartridge so that it evaporates. Some electronic cigarettes also have an indicator light at the end that glows when the user draws on the device in order to resemble a lit cigarette more closely. Made of a blend of nicotine and a range of possible flavours, a key characteristic of this smokeless nicotine product is that it is inhaled or ‘smoked’ insofar as the product produces a strong, rich vapour that feels like smoke. Another characteristic is that consumers are able to select cartridges containing their desired nicotine level from zero to high.

Box 3.2 'Real' smokeless cigarette by Smokefree Innotec, Inc.

Smokefree Innotec (SFI) has developed a tobacco-free cigarette alternative that aims to provide the tobacco flavour and nicotine enjoyment smokers derive from cigarettes, without producing the smoke that could irritate others. Real smokeless is different from electronic cigarettes in that it uses a traditional cigarette-like filter, into which the nicotine and flavour are injected by a patented nanobead technology, developed by AHN Biotechnology GmbH in Nordhausen, Germany. The device begins to warm incoming air as the smoker inhales, and the nicotine and flavour evaporate within the filter. The mix is then inhaled by the smoker, without subsequent smoke exhalation.⁵⁰ Real Smokefree currently comes in two flavours: Virginia Blend (regular tobacco with a slight fruity after-taste) and Cool Mint (with a strong menthol flavour). Components are produced and assembled in Germany and China, and SFI's technology patent covers 34 European countries (including all EU Member States).⁵¹

As an alternative to the electronic cigarette, the Smokeless Cigarette Company (TSCC) supplies the product Similar.⁵² It is a disposable heat-free, smoke-free device resembling a regular cigarette. It consists of a piece of filter wrapped around tiny molecular capsules that hold nicotine and food grade flavours. This filter is contained within normal cigarette paper, through which users inhale the nicotine-flavour substance. The product does not emit any vapour or known carcinogens into the air. Production currently takes place in Germany, and the product appears to be available by purchase on airline flights (eg Ryanair) as well as on the internet or at promotional events (eg product stalls at railway stations), as are indeed other products such as electronic cigarettes (see also Chapter 4).

3.3.2 Availability, accessibility and usage of inhaled smokeless nicotine products

We identified at least 40 brand names for electronic nicotine delivery systems, electronic, green and vapour cigarettes during our first exploratory stage of reviewing the evidence.^{53 54} Given the large variety of brands, ingredients vary. For example, an analysis by the US Food and Drug Administration found considerable variation as to the nicotine contents of 18 products reviewed, in addition to presence of other ingredients such as tobacco constituents and other substances.⁵⁵

Ayers et al (2011) tracked the rise in popularity of electronic nicotine delivery systems (ENDS) by surveying and monitoring online search queries in Australia, Canada, the UK and the US.²⁴ The authors found that online popularity of ENDS has surpassed that of *snus* and nicotine replacement therapies (NRTs) and other smokeless nicotine products; they suggested that ENDS are used to bypass or quit in response to smoking restrictions, given the association between the popularity of ENDS and stronger tobacco control. However, the authors noted that while query surveillance can be considered a valuable real-time method to evaluate the diffusion of new health products, popularity measured by increased online search queries may be a poor proxy for uptake by users in practice. Using an online survey of 81 ever-users of electronic cigarettes in 2009, Etter (2010) found that among respondents who resided in Belgium, Canada, France or Switzerland, the product was most frequently reported as a means to quit smoking, with less frequent motivations including to continue smoking in smoke-free places or not to disturb others with smoke.⁵⁶ Similar motivations were reported in a more recent internet survey of some 3,500 visitors, mostly from Canada, France, Switzerland, the UK and the US, to websites and online discussion forums on electronic cigarettes and smoking cessation.⁵⁷ While providing useful insights into the reasons for using ENDS, the self-selection of participants is likely to skew

the findings (the direction of which remains uncertain however), and they are not easily generalisable.

3.3.3 **Orally consumed smokeless nicotine products: nicotine lollipops, mints, lozenges, wafers and drinks**

Smokeless nicotine products for oral consumption include dissolvable nicotine lollipops, mints, lozenges, wafers and drinks. All of these products resemble non-nicotine versions of such sweets, albeit with added nicotine.

Nicotine lollipop: A skewered hard candy in varying flavours with added nicotine. Sucking the lollipop leads to the release of small amounts of nicotine, which are directly absorbed through the mouth and taken up in the bloodstream. Examples include NicoStop Lollipop, produced by Ashland Discount Drugs, NicoPop and Likatine (all produced and sold in the US). Lollipop products can include nicotine salicylate combined with a sweetener base (eg sugar or stevia extract) and added flavours (eg strawberry, watermelon, lemon-lime, raspberry, grape, cherry, butterscotch, spearmint).⁵⁸⁻⁶⁰

Nicotine mint or lozenge: Nicotine lozenges resemble small pills or pastilles and come in different flavours. They are fully dissolved in the mouth on the inside of the cheek or under the tongue. Sucking the lozenge releases the nicotine, which is taken up in the bloodstream through mouth tissues. The most common products are typically authorised as NRT (see also Section 5.3). Commit Lozenges, Nicotinell and NiQuitin are examples of brands. The product is usually available in packs containing 36 or 72 lozenges. The active ingredient contained in Commit Lozenges is nicotine polacrilex (1mg, 2mg or 4mg). Other inactive ingredients may include (depending on the flavour): aspartame, calcium polycarbophil, magnesium stearate, potassium bicarbonate, mannitol, sodium alginate, xanthan gum and sodium carbonate.

Nicotine cream: A resin-based formula containing nicotine is applied to the gums thereby providing rapid absorption (in 5–10 min) of nicotine into the bloodstream. According to industry, one small drop of nicotine cream is placed on the inside of a person's cheek using a unit-dose applicator; the product is currently tested in clinical trials for consideration as NRT product in the US.⁶¹

Nicotine wafer: Edible rice or starch paper printed with nicotine-infused edible ink and dissolved under the tongue, thus allowing the nicotine to be absorbed directly into the bloodstream through the mouth. One brand is NicoVar with each wafer reported to contain 1.45mg of nicotine.⁶² A key characteristic of the product is that it is thin and melts on the tongue after 3 minutes. Nicotine wafers can be purchased directly from the manufacturer via the internet.

Nicotine drink: A drink containing nicotine, which is absorbed through the digestive system. We identified two brands for this category of smokeless nicotine products: Nic Lite (India) and SJ XXX Energy Nicofix (US). Nic Lite, for example, contains 4mg caffeine per serving. A key characteristic is that it is an energy drink formulated with nicotine to reduce nicotine urge but also containing brain and body vitalisers (allegedly to maintain healthy body metabolisms). It is marketed for smokers, but is suggested to also be tasty for non-smokers.⁶³

Nicotine water (NicoWater): According to Weiss and Smith-Simone (2010), nicotine-infused water was manufactured by Nico International Inc, but the product is no longer commercially available.⁶⁴

Nicotine mouth spray: Nicotine spray consists of nicotine base dissolved in a solution comprising ethanol, glycerine water plus flavouring and buffering agents. It is to be sprayed between users' cheek and gums.⁶⁵ We identified one brand (Zonnic) that is manufactured by Niconovum AB in Sweden and marketed as NRT; it contains 1mg nicotine per dose (at approximately 200 doses per can).⁶⁶ Niconovum is part of Reynolds American Inc., US.

3.3.4 **Availability, accessibility and usage of orally consumed nicotine products**

Nicotine drinks and sweets appear to be more commonly sold in North America and Asia than in Europe. Commit lozenges are more common in the US, and available through a number of online retailers (eg Drugstore.com and Amazon.com) as well as local merchants such as Walgreens, Target, Rite Aid and Costco. Prices vary by producer, retailer and quantity per package, but a typical price for a 72-lozenge package is Target's price of US\$34.29.⁶⁷ NiQuitin is more common in Europe, and accessible online directly from the manufacturer, GlaxoSmithKline, at £15.96 for a 72-lozenge package of 2mg lozenges⁶⁸ or through (local branches of) online pharmacies accessed via internet retailer Amazon, such as UK-registered One Click Pharmacy, at a slightly lower price (£11 or €12.76).⁶⁹ Nicotine wafers, such as NicoVar, are available online although their accessibility in Europe is uncertain.⁶² Zonnic nicotine mouth spray is marketed in Denmark and Sweden; sold as a medicinal product, it is available in pharmacies only.⁷⁰

3.3.5 **Dermally applied smokeless nicotine products: nicotine toothpaste, toothpick, creams, balms and condoms**

Nicotine products that are characterised by the transmission of nicotine through the skin (dermal). They include: nicotine toothpaste, nicotine creams or (lip) balms, toothpicks and nicotine condoms.

Nicotine toothpaste: Nicotine toothpaste contains nicotine as well as traditional and natural ingredients. The paste is used for brushing teeth.

Nicotine toothpick: Toothpicks infused with nicotine-containing solution (4mg). A key characteristic is its advantage of having a dental hygiene function and also the user's ability to manipulate a cigarette-like object.⁷¹ However, current patents for the invention classify this product as NRT.

Nicotine cream or balm: Nicotine creams are water-soluble clear gels containing natural tobacco extract. Specific balms include lip balms consisting of a mix of nicotine salicylate, natural sweeteners and flavourings in a sugar-free base. According to information provided by product websites for brands such as NicoFix and Nicogel, the use of nicotine creams requires two to four pumps to be placed in the palms of a user's hands as a way to satisfy nicotine craving from one to four hours. A bottle of nicotine cream provides up to 100 servings.⁶¹

Nicotine condom (transdermal nicotine prophylaxis): A condom laced with a standardised, patented extract from the stems of *Nicotiana* (Nicogel®), in combination with a transdermal delivery system whereby nicotine is absorbed through the skin. A key

characteristic of this product is that it incorporates a lubricating silica-based gel on the inside of the condom that produces a slight numbing sensation for the user and is meant to prolong sexual activity. Produced by Swedish company Pharmacia Latex Aktiebolaget, the product is also referred to as 'Hooker NRT'.

3.3.6 **Availability, accessibility and usage of dermally applied nicotine products**

References to availability and usage of dermally applied nicotine products are scarce. We identified mentions of interest in such products on online nicotine user forums, but there is little reliable quantitative data on availability and use.

CHAPTER 4 **Marketing of novel and emerging tobacco, nicotine or related products: key informant interviews**

This chapter reports on the marketing of novel and emerging tobacco, nicotine or related products as identified from a scoping review of industry trade journals and magazines, manufacturer and retailer websites and press releases, and interviews with key informants representing manufacturers and retailers of electronic cigarettes and smokeless tobacco products.

4.1 **Overview**

The development of ‘novel’ tobacco products, particularly by those manufacturers with the largest market shares, tends to focus less on genuinely new or different products, but primarily on innovation and newly evolving variations of traditional tobacco products (cigarettes, cigars and chewing tobacco).^{19 20} These products may include additions such as filters with special features (eg glamour filters, reduced odour), flavouring (eg menthol), improved paper textures, and new packaging or ‘special editions’ of regular products for collectors. It is argued that these ‘innovations’ largely serve as a new form of marketing in jurisdictions where marketing is otherwise restricted.⁷² Another currently popular approach appears to be in the development of biodegradable cigarettes aimed at environmentally conscious consumers. According to market research firm Euromonitor International, “In a business where marketing is restricted and the leading brands have been around for a long time, it is generally preferred to make the new product a variant of an existing brand with international appeal.”²¹

There appears to be a consensus among the market-leading tobacco manufacturers that tobacco is a ‘consumer-led’ business. Major product changes are made only after extensive ‘consumer testing’, which British American Tobacco, for example, carries out through a professional agency.⁷³ Visual advertising seems to emphasise a certain physical feel of the product and a social context of use that consumers enjoy, which might lessen attraction to more ‘novel’ products without these attributes. At the same time, British American Tobacco has very recently launched its own subsidiary company ‘Nicoventures’⁷⁴ for the purpose of developing non-tobacco nicotine delivery products,⁷⁵ with similar moves pursued by Philip Morris International,⁷⁶ although there is no indication of the timing for entering the market with a new product. The product is expected to provide an alternative

to existing cigarette substitutes, such as electronic cigarettes, nicotine patches and gums, so as to better meet the “sensorial, emotional and physiological needs of smokers ... In the UK there are about 10 million smokers – and only 150,000 of them buy nicotine products, so something is not working.”⁷⁵ It is thought that this move of leading tobacco manufacturers is motivated by the hope to “capitalise on the £2.2 bn [...] global market for smoking cessation products, but also to form products so compelling for smokers that they could also target the £263 bn global tobacco market”,⁷⁶ although these developments are very recent and it is uncertain to what extent the tobacco industry will engage in them.

Some general points on novel nicotine product marketing

Executives representing manufacturers and retailers of smokeless nicotine delivery systems such as electronic cigarettes interviewed for this study indicated that transnational tobacco companies tend to rely more heavily on media activity than advertising to communicate to consumers, because of the advertising bans that are in place in many countries. The tendency may carry over to novel nicotine products, with concerns over existing or impending regulation. This emphasis on ‘public relations’ approaches has also led to intensive use of online marketing venues, such as social networking sites, website forums, interactive message boards and email lists, in order to attract and grow a customer base. Only larger manufacturers tend to have the resources required to finance large marketing and lobbying campaigns (eg representatives based in Brussels, membership in the European Smokeless Tobacco Council (ESTOC)), and because many producers of novel nicotine products are smaller companies, online venues appear to have become the marketing approach of choice.

Regarding regulation, respondents expressed concerns about electronic cigarettes in Europe being situated in some form of ‘no-man’s land’ between pharmaceutical products, tobacco and consumer goods. While acknowledging the need for standards in ingredients to ensure consumer safety (“Of course they need to be regulated in some capacity”), one respondent highlighted the need for EU-wide supervision and that clear regulation would allow retailers to sell nicotine products more easily as there is currently confusion regarding legal boundaries surrounding marketing and internet sales. Because of this confusion for both consumers and retailers, one respondent further noted that electronic cigarette retailers in Europe are not selling very much and that manufacturers are generally not making much of a profit, “even if they are saying otherwise”.

The target demographic

According to product websites and industry representatives interviewed for this study, the customer demographic targeted by manufacturers of novel smokeless tobacco, nicotine or related products is adult, current smokers, who are looking for a reduced-harm alternative. They claim little interest in attracting new users; however, there is not much sound evidence as to whether this is indeed the case. Although pharmacies and convenience stores can require identification to prove a customer’s age, there is less oversight of online purchases. Manufacturers and retailers may formally maintain a policy of selling only to those aged 18 and over, but possession of a credit card or a PayPal account is frequently seen as the only indicator of the adult status of their customers.

4.2 **Marketing of specific products: combusted tobacco-free products**

There is little published data on the marketing of combusted tobacco-free products. Identified information predominantly concerns the price of herbal cigarettes as described in Section 3.1.3.

Sales of waterpipes, according to shisha manufacturers, as noted earlier, are rising in Europe, primarily in countries with ‘established markets’ such as France, Germany, Spain and Switzerland.⁷⁷ Manufacturers based in the United Arab Emirates, Egypt and India note that smoking bans in several European countries have not had an effect on sales because shisha is often smoked in open air cafés or other open areas. The number of home users tends to increase where a country implements a smoking ban in public places, although evidence from the UK smoke-free legislation does not support this assertion.⁷⁸ Current shisha marketing seems to focus on promoting a certain cultural feel and flavour variety.⁷⁷

Tobacco Journal International (2009) also reported on the opportunities for flavour manufactures in selling to shisha companies, noting international trends toward natural or ‘organic’ flavours.⁷⁹ The director of the tobacco business unit group at flavour manufacturer Mane is quoted reporting increasing volume demand for hookah/shisha in general, and in particular for “new, creative flavour tonality themes”.⁸⁰

4.3 **Marketing of specific products: smokeless tobacco products**

As noted in the preceding chapter, available data on smokeless tobacco products typically refer to chewing tobacco and snuff (dry and moist) only. For example, data reported by Euromonitor International (2008) indicate the projected growth for these products globally as the fastest growing sector, at 30 percent both in volume and value, between 2007 and 2012, compared with a projected growth in global sales of cigarettes at 20 percent.¹⁹ This figure may be revised downwards with Euromonitor’s latest data, suggesting that global cigarette consumption has now started to decline. According to Euromonitor data, in 2008, the smokeless tobacco market was dominated by Asian-style chewing tobacco, at 43.3 percent, followed by US-style moist snuff (‘dip’) (36.3 percent) and Swedish-style *snus* (12.6 percent), with the remainder formed by other chewing tobacco and dry snuff.²² Most of the projected growth in the smokeless tobacco product market is projected to take place in the US, where in 2007 these products accounted for 4 percent of the US tobacco products market. Globally, in 2008, in value, smokeless tobacco accounted for about 2.2 percent of the tobacco products market.²²

Similar to nicotine-only products (see below), smokeless tobacco products are often promoted as a way to consume nicotine where smoking is prohibited. For example, Denmark-based Oliver Twist produces small tobacco pellets in a variety of flavours, describing them as “good products to use where smoking is not permitted”.⁸¹ The company’s website reports that the Oliver Twist brand is a market leader in Denmark, Norway and Sweden, and is sold in a number of European countries and the US.

As with nicotine-only products, smokeless tobacco is also commonly promoted as a reduced-harm alternative to smoking (Box 4.1). According to representatives from a

smokeless tobacco company interviewed for this study, the international trend toward regulation of novel tobacco and nicotine products is driven by “cultural, moral and political factors”. They feel that because the major tobacco industry players have a history of being regarded as dishonest, it may be more challenging to persuade governments and the public that novel products could possibly help smokers: “There is a prevailing ‘quit or die’ mentality,” explained one respondent, “[t]he instinct is not to consider [the potential for] harm reduction.”

Box 4.1 A closer look: Star Scientific

Star Scientific, a US producer of smokeless tobacco lozenges, is a strong proponent of harm reduction. The company’s marketing approach is that science should drive tobacco product manufacturing, and it promotes its products as containing fewer toxins than other tobacco products. The company has begun producing versions of its primary products Ariva and Stonewall with ultra-low levels of tobacco specific nitrosamines (TSNAs).³⁸ This has become possible with a recent decision by the US Food and Drug Administration (FDA), which ruled that Ariva-BDL and Stonewall-BDL are not tobacco products as classified in Chapter IX of the Federal Food, Drug, and Cosmetic (FD&C) Act. Thus, the company is free to market and advertise these products without the restrictions that would otherwise apply. Specifically, it can market its products as ‘modified risk’ because of their low levels of TSNAs.⁸²

The products are currently only sold in the US, and primarily over the counter through chemist shops and convenience stores. The intended customer demographic is adult current smokers. Star Scientific relies on chemists and store clerks to check proof of age on purchase, and customers cannot buy their products direct from the Star Scientific website. It should also be noted that from June 2010, the purchase of smokeless tobacco products online has become difficult as shipment of tobacco products (cigarettes and smokeless tobacco products), using the US postal service, have been banned within, into and outside the US with the 2010 Prevent All Cigarette Trafficking Act (PACT) law.⁸³ Products can still be shipped using alternative routes through international carriers such as UPS but the recipient will have to be ID-checked on arrival of the product. As with European retailers of smokeless tobacco products, efforts to prevent purchase by young people consist primarily of messages on packaging and websites, which state that the products are not for minors.

SOURCE: Manufacturer information; interview data

4.4 Marketing of specific products: smokeless nicotine products

As indicated above, the most commonly used marketing message by retailers of smokeless tobacco, nicotine or related products is one of ‘harm reduction’: promoting products as safer yet satisfying alternatives to smoking tobacco. This approach is used by retailers in Europe and internationally (Box 4.2). In 2008, marketers of ENDS in the US noted that ENDS were endorsed by the World Health Organization (WHO), which it then denied.⁸⁴ The FDA in the US recently accepted a US Court of Appeals ruling that electronic cigarettes are to be regulated as tobacco products,⁸⁵ and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK consulted the public on whether they should be regulated as medicinal products.⁸⁶ The MHRA recently communicated its decision to undertake further scientific and market research to better understand the actual use of existing nicotine products in the marketplace and their effect on smoking cessation, as well as to model the potential impact of regulating these products under medicines

regulation on public health outcomes. A final decision on the regulation of nicotine-containing products is expected for spring 2013.

Box 4.2 A closer look: the Electronic Cigarette Company

The Electronic Cigarette Company (TECC) is a UK-based electronic cigarette and accessory retailer. Founded as an eBay seller in around 2006, the company now has a £1 million turnover a month. It sells approximately 10,000 e-cigarette kits per month directly to consumers, and additionally has various resellers selling their products, making total sales estimates for kits of a figure of 150,000 annually.

As with most European electronic cigarette retailers, cartridges are imported from China and then assembled into a product that reflects the retailer's branding. Most companies import nicotine fluid as well, often from within Europe. TECC strongly emphasises its variety of flavours on its websites.⁸⁷

TECC primarily sells online and recently launched a retail outlet for its 'Totally Wicked' brand. This shop is promoted as the UK's first electronic cigarette retail outlet, where customers can enjoy complimentary, freshly made coffee and biscuits while trying different liquid or vapour flavours—a 'try before you buy' approach.⁸⁸ TECC has also launched an 'e-smoking lounge' in Florida and would like to open some in the UK within the next year or so. Although the company currently sells only within the UK and the US, it is looking to expand to Germany, Portugal and Spain.

The loyal customer

TECC's online chat forums, mailing lists and use of social media (Facebook, Twitter, YouTube) are its primary medium for marketing. The creation of an online viral marketing community, in which the customers essentially spread the word, has resulted in fast growth for TECC as well as a loyal customer base. About 100,000 users have signed up to TECC's email distribution list.

Openness and transparency

TECC notes that it aims for openness and transparency in all of its dealings with customers (eg inviting feedback and product suggestions) as well as regulators. TECC views e-cigarettes as a consumer leisure product, not a medicine nor a tobacco product, and therefore does not consider that these products should be regulated as such. TECC responded to the UK MHRA's December 2010 public consultation on the potential regulation of e-cigarettes, which is posted on the MHRA's website for all stakeholders to view, as are most responses to the consultation.⁸⁶ It may be noteworthy that two larger retailers, Nicocigs and E-lites, responded to the consultation in favour of requiring regulation to some degree.

SOURCE: Manufacturer information; interview data

Industry representatives interviewed for this research noted that, in their view, the lack of combustion in nicotine-only products results in the consumption of fewer toxins, and so presents reduced risk for consumers. At the same time, as suggested by one interviewee, products that seem too pharmaceutical or clinical may be unattractive to consumers, who, it is claimed, desire not only a nicotine rush, but the satisfaction that comes from the familiar feel and tastes of traditional tobacco products. However, the evidence to support this claim remains uncertain. Smokefree Innotec advertises its Real smokeless product (see Box 4.3) as having "the look and feel of a real cigarette (including heating sensation)" and "a more genuine taste than other electronic cigarettes because of its cigarette-like filter".⁵⁰

Box 4.3 A closer look: Smokefree Innotec

Founded in 2007, Smokefree Innotec (SFI) is an international producer and retailer of electronic cigarettes. Its headquarters are in Irvine, California, and Antwerp, Belgium. Company stock is publicly traded on NASDAQ:SFIO. SFI has developed the Real smoke-free brand (Section 3.3) and also sells Smoker's Option, a smoke-free product without nicotine, which comes in regular, cinnamon and menthol flavours.

Distribution SFI began selling in the US in 2010, directly through its website and third-party retailers such as gas stations and convenience stores. Trade in Europe is not directly through the SFI website because of the differing regulatory statutes and restrictions in Member States. Instead, SFI is currently entering formal links with drug stores, retail (including online) distributors and vending machine operators within selected Member States that have not issued bans on the sale of nicotine delivery devices. These include France, Italy, Spain, the UK, and the Nordic countries. They are also interested in selling at European airport shops. The suggested retail price for the Real smokeless starter kit is €99, with filter packs at €7.50.

Marketing

The company reportedly targets male and female smokers over the age of 30 years who are looking for nicotine consumption alternatives. Most of SFI's visible European marketing is targeted at investors. SFI's website marketing is focused on corporate facts, description of technology and stock information. However, company representatives regularly attend conferences to introduce and display SFI's products, including the 2009 Belgian Horeca Fair in Ghent, at which a prize draw was held for visitors to win a five-star mini-cruise in cooperation with Belgium Cruise Centre. Similar to other electronic cigarette producers, SFI very much sees its products as 'fast moving consumer goods' rather than pharmaceutical or tobacco products, or "overpriced gadgets for the elite".⁸⁹ The company aims at developing a European consumer-focused website in the near future, along with an online shop.

SOURCE: Manufacturer information; interview data

One respondent expressed a strong belief that electronic cigarettes have an expanding market throughout Europe, adding that "it is a very young market, and [whichever brand] gets there first, the 'first movers' are likely to be the ones to stick in consumers' minds". The role of viral marketing in promoting novel tobacco, nicotine or related products has been studied in relation to RJ Reynolds Company for its Eclipse cigarettes. Anderson and Ling (2008) analysed previously confidential tobacco industry documents and multimedia materials to explore such marketing techniques, finding them to be "particularly useful to promote new tobacco products such as Eclipse that have limited appeal and need a highly motivated audience of early adopters and acceptors".⁹⁰ The authors suggest that viral marketing strategies support tobacco companies in several ways by enabling or allowing them to: (i) evade the mass rejection following mass promotion; (ii) circumvent marketing restrictions; and (iii) benefit from health claims made by consumers.

Box 4.4 A closer look: The Smokeless Cigarette Company

The Smokeless Cigarette Company (TSCC), based in Kent, UK, supplies an alternative to the electronic cigarette. Its product Similar is a disposable heat-free, smoke-free device resembling a regular cigarette (Section 3.3).⁵²

Distribution

TSCC takes a reportedly 'unique approach to business' in that it views itself as a partner to airlines rather than solely a producer. The company started by producing scratch cards to sell on board and maintained vendor relationships with airlines in developing a product to fit what they saw as a niche market for publicly acceptable cigarettes. They currently offer flight crew training on selling the cigarettes as well as incentives for sales.

As of 2010, TSCC reported sales of around one million Similar packs per annum. Distribution, through a company based in Cyprus, was to 33 warehouses across Europe, with sales taking place primarily on airlines and in airport shops. TSCC holds an exclusive contract with low-cost airline Ryanair, on which Similar is the only sort of smokeless cigarette sold, at a cost of €5–6 per pack. TSCC reports that its smokeless cigarettes are the third most popular product category sold onboard, following soft drinks and snacks.⁹¹ Similar cigarettes tend to sell most on flights out of Italy and Spain followed by those from France, Germany and the UK. Scandinavian flights experience the lowest sales numbers.

A 2010 news article reports that TSCC had been in discussion with a group of long-haul carriers regarding stocking its products, and that Air Astranus, El Al Israel Airlines and Gulf Air were showing interest.⁹²

Marketing

The company reportedly targets those aged 30 years and over who already use nicotine and are looking for a cigarette alternative. Like other manufacturers and retailers, TSCC does not advertise its products, because of the bans on tobacco and nicotine advertising in multiple countries. Instead, it relies heavily on public relations, including events and related publicity, media exposure and word of mouth.

As for the future, TSCC would like to see its products offered in convenience stores and believes it to be only a matter of time before electronic cigarettes and their alternatives become more well known and accepted as mainstream products. The company does not feel it has any direct competitors in Europe.

SOURCE: Manufacturer information; interview data

CHAPTER 5 **Availability, accessibility and use of novel and emerging tobacco, nicotine or related products: stakeholder survey**

This chapter reports on the results of the online survey of key stakeholders in the 27 Member States of the EU. The aim of the online survey was to collect additional information on the availability, accessibility and use as well as the regulation of novel and emerging tobacco, nicotine or related products as described in Chapter 3.

Before describing the key observations of the survey it is important to highlight some caveats. Thus, as with any survey, the quality of the information collected relies on the knowledge and opinions of respondents, which cannot readily be verified or validated. Some Member States provided multiple responses from different organisations, with differences in responses to the same question. This could either indicate a lack of knowledge on the part of some respondents and/or, more likely perhaps, indicate that knowledge about novel tobacco, nicotine or related products is patchy given that many of these products have only recently emerged on the European market and that little documented research has been undertaken so far to explore systematically their availability, usage and regulatory status throughout the EU.

Conversely, it should be noted that for those Member States that were represented by one respondent only, the information thus provided does not necessarily permit a more robust assessment of the availability, accessibility, usage and regulation of these products in the Member State concerned. These limitations should be borne in mind when interpreting the data. However, we believe that the data collected will provide a useful starting point for establishing a baseline for assessing the need for strengthening of the regulation and restrictions of these products to safeguard the health of consumers in the EU.

5.1 **Background information on respondents**

A total of 66 respondents from 24 Member States responded to the online survey. This equates to an approximate response rate of 53 per cent.^b

^b This response rate is approximate given the number of reminders sent and the number of emails redirected to different colleagues in the organisations targeted by the survey.

Table 5.1 shows the breakdown of respondents by Member State. For the majority of Member States (17 out of 24) we received more than one response. Finland, Sweden and the UK were the countries with the highest number of responses (seven for Finland and six for the UK and Sweden). Despite repeated attempts, we were not able to not obtain responses from Cyprus, Greece and Italy.

Table 5.1 Number of respondents by country

| Member state | Count of respondents | Proportion of respondents |
|---------------------|-----------------------------|----------------------------------|
| Austria | 1 | 2% |
| Belgium | 1 | 2% |
| Bulgaria | 1 | 2% |
| Czech Republic | 2 | 3% |
| Denmark | 2 | 3% |
| Estonia | 2 | 3% |
| Finland | 7 | 11% |
| France | 1 | 2% |
| Germany | 4 | 6% |
| Hungary | 1 | 2% |
| Ireland | 3 | 5% |
| Latvia | 2 | 3% |
| Lithuania | 1 | 2% |
| Luxembourg | 3 | 5% |
| Malta | 4 | 6% |
| Netherlands | 2 | 3% |
| Poland | 3 | 5% |
| Portugal | 4 | 6% |
| Romania | 1 | 2% |
| Slovakia | 4 | 6% |
| Slovenia | 2 | 3% |
| Spain | 3 | 5% |
| Sweden | 6 | 9% |
| UK | 6 | 9% |
| Grand total | 66 | 100% |

SOURCE: RAND Europe survey, April-June 2011. Q1_Please select your country in the drop-down list below.

Table 5.2 shows the types of organisations represented by respondents. These were mainly NGOs (30 percent), ministries of health (21 percent) and medicines agencies (17 percent).

Table 5.2 Respondents by type of organisation

| Member state | Count of respondents | Proportion of respondents |
|----------------------------|-----------------------------|----------------------------------|
| NGO | 20 | 30% |
| Ministry of Health | 14 | 21% |
| Medicines agency | 11 | 17% |
| Academic organisation | 7 | 11% |
| Other, please specify: | 6 | 9% |
| Public health organisation | 5 | 8% |
| Regulatory agency | 2 | 3% |
| No response | 1 | 2% |
| Grand total | 66 | 100% |

SOURCE: RAND Europe survey, April-June 2011. Q2 Please select the type of organisation you work for from the list below.

5.2 Availability of novel and emerging tobacco, nicotine or related products per country products in EU Member States

Table 5.3 illustrates the availability of novel tobacco, nicotine or related products as reported by country of respondent(s). Where there were multiple responses from a given country, we developed an algorithm to account for potentially contradictory responses so as to enable assessment of a Member State response. Thus, where there were ‘yes’, ‘no’ and ‘don’t know’ responses, we selected ‘yes’ as the most likely ‘true’ response, based on the assumption that a ‘yes’ response is more likely to reflect certainty about a given fact.^c To indicate where such decisions were taken, we have highlighted cells in the relevant table. As noted above, this approach should not be interpreted to mean that where there was only one response for a given Member State that this response is considered more valid. On the contrary, it could be said that such responses are less robust than multiple responses for a given Member State.

Overall we find that all 24 Member States that are represented by the survey indicate availability of ENDS in their country (see also Table 5.4). Other products that appear to be widely available for purchase across Member States are herbal cigarettes (respondents from 22 Member States, with the notable exception of French respondents who stated these are not available); flavoured tobacco for use in waterpipes (respondents from 23 Member States); and herbal tobacco or herbal shisha for use in waterpipes (respondents from 22 Member States). On the other hand, nicotine drinks were not reported to be available for purchase in any Member State included here; nicotine toothpaste appeared to be only available in the UK and tobacco-infused drinks only in Romania.

^c Where one respondent answered ‘yes’ and two responded ‘no’, this response would also be assumed to be ‘yes’ overall.

Table 5.3 Novel and emerging tobacco, nicotine or related products availability by EU Member State

| Product | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Estonia | Finland | France | Germany | Hungary | Ireland | Latvia | Lithuania | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Slovakia | Slovenia | Spain | Sweden | UK |
|---|---------|---------|----------|----------------|---------|---------|---------|--------|---------|---------|---------|--------|-----------|------------|-------|-------------|--------|----------|---------|----------|----------|-------|--------|-----|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Smokeless cigarettes (non-battery operated) | d/k | d/k | d/k | N | d/k | N | Y | N | Y | d/k | Y | Y | d/k | Y | N | Y | Y | N | d/k | N | d/k | Y | Y | Y |
| Herbal cigarettes | Y | Y | d/k | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | d/k | Y | d/k | Y | Y | Y |
| Nicotine lollipops | d/k | N | d/k | N | N | Y | N | N | N | d/k | N | N | d/k | N | N | N | Y | N | d/k | N | d/k | N | N | d/k |
| Nicotine lozenges | Y | d/k | d/k | N | Y | d/k | N | N | Y | d/k | Y | N | d/k | N | Y | N | Y | Y | d/k | Y | d/k | N | Y | Y |
| Nicotine toothpick | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | d/k | N | d/k | N |
| Nicotine condoms | d/k | N | d/k | N | N | d/k | N | N | N | N | N | N | d/k | N | N | N | N | N | d/k | N | d/k | N | d/k | Y |
| Herbal tobacco or herbal shisha for use in waterpipes | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | d/k | Y | Y | Y | Y | Y | d/k | Y | Y | Y | Y | Y |
| Nicotine wafers | Y | d/k | d/k | d/k | d/k | Y | N | d/k | Y | d/k | d/k | N | d/k | d/k | N | Y | d/k | d/k | d/k | Y | d/k | Y | d/k | Y |
| Nicotine drink | d/k | d/k | d/k | N | N | d/k | N | N | N | d/k | d/k | N | d/k | N | N | N | N | N | d/k | N | N | N | d/k | d/k |
| Nicotine toothpaste | d/k | N | d/k | N | N | d/k | N | N | N | d/k | d/k | N | d/k | N | N | N | N | N | d/k | N | N | N | N | Y |
| Nicotine cream | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | N | N | N | Y |
| Nicotine spray | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | Y | N | d/k | N | N | N | N | d/k |
| Nicotine lip balm | d/k | N | d/k | N | Y | d/k | N | N | N | d/k | N | N | d/k | Y | N | N | Y | N | d/k | N | N | N | Y | Y |
| Tobacco tablets | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | Y | N | d/k | N | N | N | d/k | N |
| Tobacco pellets, sticks and strips | d/k | N | d/k | N | Y | d/k | N | N | N | d/k | N | N | d/k | N | Y | d/k | Y | N | d/k | N | N | N | Y | N |
| Tobacco water (tuibur/hidakphu) | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | d/k | Y | N | d/k | N | N | N | Y | N |
| Tobacco-infused drinks | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | d/k | N | N | Y | N | N | N | N | N |
| Red tooth tobacco powder | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | N | N | d/k | N |
| Bajjar tooth powder | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | N | N | N | Y |
| Gul (Gadakhu) tooth powder | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | d/k | N | d/k | N | N | N | N | Y |
| Tobacco toothpaste (Quiwam) | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | d/k | N | d/k | N | N | N | N | Y |

| Product | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Estonia | Finland | France | Germany | Hungary | Ireland | Latvia | Lithuania | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Slovakia | Slovenia | Spain | Sweden | UK |
|--|---------|---------|----------|----------------|---------|---------|---------|--------|---------|---------|---------|--------|-----------|------------|-------|-------------|--------|----------|---------|----------|----------|-------|--------|----|
| Mishri tooth powder | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | N | N | N | Y |
| Tobacco toothpaste (creamy snuff) | d/k | N | d/k | N | N | d/k | N | N | N | d/k | N | N | d/k | N | N | N | N | N | d/k | N | N | N | N | Y |
| Tobacco-infused ingredients of cocktails | d/k | N | d/k | N | Y | d/k | N | N | N | d/k | N | N | d/k | N | N | N | d/k | N | d/k | N | N | N | N | Y |

SOURCE: RAND Europe survey, April-June 2011. Q3 Which of the following products are available (both formally and informally) in your country? For definitions of the products below, please place your mouse over the product and a definition will appear.

NOTE: Y – Yes; N – No; d/k – Don't know

Table 5.4 shows where available novel tobacco, nicotine or related products can be purchased in Member States. It is worthwhile noting that pharmacies appear to represent the main location for the purchase of selected nicotine products in some Member States. For example, in the case of ENDS and herbal cigarettes, respondents from, respectively, seven and six Member States report that these products are available in pharmacies. Many of these products are also available for purchase from tobacco shops, including herbal products such as herbal cigarettes and herbal tobacco for use in waterpipes. The most important outlet for the majority of products surveyed here appears to be the internet, however, followed closely by tobacco shops.

Table 5.4 Novel and emerging tobacco, nicotine or related products by location of purchase in EU Member States

| Product | Tobacco shops | Food shops | Pharmacies | Duty free shops | Internet | Other* |
|---|--|---|--|----------------------------|---|--|
| Electronic cigarettes, e-cigarette or ENDS | Bulgaria Czech Republic Denmark Estonia France Germany Malta Netherlands Poland Portugal Spain | Denmark Latvia Poland Portugal | Czech Republic France Ireland Malta Netherlands Spain UK | Germany Latvia Spain | Austria Belgium Czech Republic Denmark Estonia Finland France Germany Hungary Ireland Latvia Lithuania Luxembourg Malta Poland Portugal Slovakia Slovenia Spain Sweden UK | Austria Bulgaria Denmark Ireland Latvia Poland Slovakia Slovenia Spain UK |
| Smokeless cigarettes (non-battery operated) | Finland Spain Sweden | Sweden | Netherlands Spain UK | Latvia Sweden UK | Finland Germany Ireland Latvia Luxembourg Spain Sweden UK | Germany Latvia Poland Spain UK |
| Herbal cigarettes | Belgium Czech Republic Denmark Estonia Finland Germany Luxembourg Malta Netherlands Portugal Slovakia Spain Sweden UK | Finland Ireland UK | Austria Finland Germany Ireland Slovenia Spain | | Austria Belgium Czech Republic Estonia Finland Germany Hungary Ireland Latvia Lithuania Malta Slovenia Spain Sweden UK | Czech Republic Denmark Finland Ireland Slovenia Spain Sweden |

| Product | Tobacco shops | Food shops | Pharmacies | Duty free shops | Internet | Other* |
|---|---|-------------------|------------------------|------------------------|--|--|
| Nicotine lollipops | Estonia | | Poland | | Estonia | |
| Nicotine lozenges | UK | | Germany Malta UK | | Malta UK | |
| Nicotine toothpick | | | | | | |
| Nicotine condoms | | | | | UK | |
| Herbal tobacco or herbal shisha for use in waterpipes | Belgium Bulgaria Czech Republic Estonia Finland France Germany Latvia Luxembourg Malta Netherlands Poland Portugal Slovakia Spain Sweden UK | UK | | Slovenia | Austria Belgium Czech Republic Estonia Finland Hungary Ireland Latvia Malta Poland Slovakia Slovenia Spain Sweden UK | Czech Republic Denmark Hungary Ireland Spain Sweden UK |
| Nicotine wafers | | | | | | |
| Nicotine drink | | UK | | | UK | |
| Nicotine toothpaste | | UK | | | UK | |
| Nicotine cream | | | | | | Poland |
| Nicotine spray | | UK | | | | |
| Nicotine lip balm | | | | | | |
| Tobacco tablets | Denmark Sweden | Denmark | | Denmark | Denmark Sweden | Denmark |
| Tobacco pellets, sticks and strips | Poland Sweden | Sweden | | | Sweden | Sweden |
| Tobacco water (tuibur/hidakphu) | | | | | | |
| Tobacco-infused drinks | | | | | | |
| Red tooth tobacco powder | UK | UK | | | UK | |
| Bajjar tooth powder | UK | UK | | | UK | |
| Gul (Gadakhu) tooth powder | UK | UK | | | UK | |
| Tobacco toothpaste (Quiwam) | UK | UK | | | UK | |
| Mishri tooth powder | UK | UK | | | UK | |

| Product | Tobacco shops | Food shops | Pharmacies | Duty free shops | Internet | Other* |
|--|---------------|---------------|------------|-----------------|----------|--------|
| Tobacco toothpaste (creamy snuff) | Denmark UK | Denmark UK | | | UK | |
| Tobacco-infused ingredients of cocktails | | Germany | | | | |

SOURCE: RAND Europe survey, April-June 2011. Q8 Below is the list of products which can be purchased from physical locations and are not authorised as nicotine replacement therapies (NRTs) in your country based on your answers to the previous question. Can you please indicate where these products can be purchased in your country?

NOTE: * 'Other' were reported for (i) ENDS and smokeless cigarettes: airplane, shopping centres, mobile sales outlets in railway stations, special points of sale; (ii) herbal cigarettes: alternative health shops, ethnic and organic shops, parapharmacy shops, herbal shops, selected grocers; (iii) flavoured/herbal tobacco for use in waterpipes: alternative health shops, ethnic shops, parapharmacy shops, waterpipes bar, shisha bars, tea rooms; (iv) nicotine cream: cosmetic shops; (v) tobacco lozenges, pellets and strips: service stations.

5.3 Tobacco, nicotine or related products classified as NRT in EU Member States

Survey respondents were asked to indicate whether the products they had identified as being available for purchase in their country were classified as a NRT.

Table 5.5 summarises the responses we received from Member States regarding the NRT classification of available nicotine and tobacco products. Only six products were indicated as being classified as NRTs in a number of Member States. These are: ENDS, nicotine lozenges, nicotine spray, nicotine tablets and nicotine pellets, sticks and strips. ENDS, the most commonly available product in all 24 Member States for which we received a response, appear to be authorised as a NRT in three Member States only: Ireland, Poland and Portugal. In contrast, respondents from ten Member States reported that nicotine lozenges were classified as a NRT. Sweden was the only country where smokeless, non-battery operated cigarettes appear to be classified as a NRT.

Table 5.5 Novel tobacco, nicotine or related products by NRT classification in EU Member States

| Product | Member States in which the product is authorised as NRT |
|---|---|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | Ireland, Poland, Portugal |
| Smokeless cigarettes (non-battery operated) | Sweden |
| Herbal cigarettes | - |
| Nicotine lollipops | - |
| Nicotine lozenges | Austria, Denmark, Germany, Ireland, Malta, Poland, Portugal, Slovakia, Sweden, UK |
| Nicotine toothpick | - |
| Nicotine condoms | - |
| Flavoured tobacco for use in waterpipes | - |
| Herbal tobacco or herbal shisha for use in waterpipes | - |
| Nicotine wafers | - |
| Nicotine drink | - |
| Nicotine toothpaste | - |
| Nicotine cream | - |

| Product | Member States in which the product is authorised as NRT |
|--|--|
| Nicotine spray | Denmark, Luxembourg, Sweden, UK |
| Nicotine lip balm | - |
| Tobacco tablets | Malta, Poland |
| Tobacco pellets, sticks and strips | Poland |
| Tobacco water (tuibur/hidakphu) | - |
| Tobacco-infused drinks | - |
| Red tooth tobacco powder | - |
| Bajjar tooth powder | - |
| Gul (Gadakhu) tooth powder | - |
| Tobacco toothpaste (Quiwam) | - |
| Mishri tooth powder | - |
| Tobacco toothpaste (creamy snuff) | - |
| Tobacco-infused ingredients of cocktails | - |

SOURCE: RAND Europe survey, April-June 2011. Q7 Below is the list of products which you have indicated can be purchased from physical locations within your country, based on your answer in the previous question. Which of the following products are authorised as nicotine replacement therapies (NRTs) in your country?

5.4 Regulation of novel and emerging tobacco, nicotine or related products in EU Member States

5.4.1 Product availability by regulatory status

Table 5.6 shows the available products by regulatory status for each country of respondents. As with Table 5.3, where multiple respondents from one Member State provided different answers, this has been highlighted through greyed out cells. In this case, responses indicating a product was 'regulated' were considered the dominant response.

Table 5.6 Novel tobacco, nicotine or related products by regulatory status in EU Member States

| Product | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Estonia | Finland | France | Germany | Hungary | Ireland | Latvia | Lithuania | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Slovakia | Slovenia | Spain | Sweden | UK |
|---|---------|---------|----------|----------------|---------|---------|---------|--------|---------|---------|---------|--------|-----------|------------|-------|-------------|--------|----------|---------|----------|----------|-------|--------|-----|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | R | R | U | U | R | R | R | U | U | B | U | U | d/k | d/k | R | U | U | R | n/a | U | U | U | R | R |
| Smokeless cigarettes (non-battery operated) | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | U | n/a | U | U | n/a | d/k | R | n/a | R | n/a | n/a | n/a | n/a | U | R | U |
| Herbal cigarettes | U | R | n/a | U | U | U | R | n/a | R | d/k | U | R | d/k | R | R | n/a | R | U | n/a | U | U | U | R | U |
| Nicotine lollipops | n/a | n/a | n/a | n/a | n/a | U | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Nicotine lozenges | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | DK | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Nicotine toothpick | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Nicotine condoms | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | U |
| Herbal tobacco or herbal shisha for use in waterpipes | R | R | U | U | U | U | R | U | U | d/k | U | U | n/a | R | R | n/a | R | R | n/a | U | U | U | R | R |
| Nicotine wafers | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Nicotine drink | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Nicotine toothpaste | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | U |
| Nicotine cream | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Nicotine spray | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | d/k |
| Nicotine lip balm | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Tobacco tablets | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | R | n/a |
| Tobacco pellets, sticks and strips | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | R | n/a | n/a | n/a | n/a | n/a | R | n/a |
| Tobacco water (tuibur/hidakphu) | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Tobacco-infused drinks | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Red tooth tobacco powder | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Bajjar tooth powder | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Gul (Gadakhu) tooth powder | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Tobacco toothpaste (Quiwam) | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Mishri tooth powder | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |
| Tobacco toothpaste (creamy snuff) | n/a | n/a | n/a | n/a | U | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | R |

| Product | Austria | Belgium | Bulgaria | Czech Republic | Denmark | Estonia | Finland | France | Germany | Hungary | Ireland | Latvia | Lithuania | Luxembourg | Malta | Netherlands | Poland | Portugal | Romania | Slovakia | Slovenia | Spain | Sweden | UK |
|--|---------|---------|----------|----------------|---------|---------|---------|--------|---------|---------|---------|--------|-----------|------------|-------|-------------|--------|----------|---------|----------|----------|-------|--------|-----|
| Tobacco-infused ingredients of cocktails | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | DK | n/a | n/a | n/a | n/a | n/a | R | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |

SOURCE: RAND Europe survey, April-June 2011. Q9 Can you please indicate if these products are regulated, unregulated but available or banned in your country?

NOTE: R – Regulated; U – Not regulated but available; B – Banned or prohibited; d/k – Don't know; n/a – Data not available/no response

Table 5.6 shows that only one product appears to have been banned, this is reportedly the case for ENDS in Hungary. Respondents from Malta indicated that all products surveyed are regulated in their country. Although, as shown in Table 5.3, ENDS have been reported as being available in all Member States for which we received a response, this product appears to be regulated in nine Member States only. Respondents from ten Member States indicated that herbal cigarettes, although available for purchase in 22 of the countries for which we received a response, were not regulated in their country.

Table 5.7 further disaggregates novel tobacco and nicotine product by the type of regulation they are covered under in the different Member States. The numbers in brackets represent the number of respondents who indicated a given product was regulated by a certain type of regulation in a given Member State. For example, four respondents in Finland stated that ENDS were covered under tobacco regulation.

Table 5.7 Novel nicotine and tobacco products by the type of national regulation under which they are regulated

| Country | Tobacco regulation | Food regulation | Pharmaceutical regulation | Other regulation |
|----------------|---|--|---------------------------|---|
| Austria | Herbal tobacco or herbal shisha for use in waterpipes (1) | | ENDS (1) | |
| Belgium | | | | |
| Bulgaria | | | | |
| Czech Republic | | | | |
| Denmark | Tobacco tablets (1) | | ENDS (1) | |
| Estonia | | | ENDS (1) | |
| Finland | ENDS (4) Smokeless cigarettes (non-battery operated) (2) Herbal cigarettes (4) Herbal tobacco or herbal shisha for use in waterpipes (2) | Herbal cigarettes (3) Herbal tobacco or herbal shisha for use in waterpipes (1) | ENDS (5) | Smokeless cigarettes (non-battery operated) (2) |
| France | | | | |
| Germany | | | | |
| Hungary | | | | |
| Ireland | | | | |
| Latvia | Herbal cigarettes (1) | | | |
| Lithuania | | | | |
| Luxembourg | Herbal cigarettes (1) Herbal tobacco or herbal shisha for use in waterpipes (2) | | | |
| Malta | ENDS (2) Herbal cigarettes (1) | | | |
| Netherlands | | | | |
| Poland | Tobacco tablets (1) Tobacco pellets, sticks and strips (1) | | | |

| Country | Tobacco regulation | Food regulation | Pharmaceutical regulation | Other regulation |
|----------|--|---|---------------------------|--|
| Portugal | Herbal tobacco or herbal shisha for use in waterpipes (1) | | ENDS (1) | |
| Romania | | | | |
| Slovakia | | | | |
| Slovenia | | | | |
| Spain | | | | |
| Sweden | Herbal tobacco or herbal shisha for use in waterpipes (1) Tobacco tablets (1) Tobacco pellets, sticks and strips (2) | Örtsnus (herbal <i>snus</i>) (1) | ENDS (1) | Herbal cigarettes (1) Herbal tobacco or herbal shisha for use in waterpipes (1) |
| UK | Red tooth tobacco powder (1) Bajjar tooth powder (1) Gul (Gadakh) tooth powder (1) Tobacco toothpaste (Quiwam) (3) Mishri tooth powder (1) Tobacco toothpaste (creamy snuff) (3) Gutkha (2) Khaini (2) Snuff (1) Makla Bouhel (1) | Herbal tobacco or herbal shisha for use in waterpipes (1) Nicotine drink (1) | | ENDS (1) Nicotine lozenge (1) |

SOURCE: RAND Europe survey, April-June 2011- Q10 Can you please indicate under which national regulation these products are regulated in your country?

Table 5.7 further illustrates that the most common type of national regulation covering any of these products is tobacco regulation, followed by food regulation and pharmaceutical regulation. Of the products indicated as available for purchase in Member States, ENDS appear to be the only products that are currently regulated under national pharmaceutical regulations. A number of products were regulated under food regulation, of which most were herbal products (herbal cigarettes, herbal tobacco for use in waterpipes and herbal *snus*). In addition, a number of products were regulated under 'other regulation' in some Member States including smokeless cigarettes (non-battery operated) in Finland and herbal cigarettes in Sweden for example.

Details of whether these products are covered fully or partially by the different types of national regulations (tobacco, food, pharmaceutical and other regulation) and the titles of the regulation in question, where available, are given in Appendix D of this report. Unsurprisingly, there is only a small amount of data concerning the level of regulation of these products as few of these products were found to be regulated and/or available in Member States.

5.4.2 Restrictions on advertising and the sale of novel and emerging tobacco, nicotine or related products in EU Member States

We were further interested in identifying whether and to what degree Member States imposed restrictions on any of the novel and emerging tobacco, nicotine or related products surveyed here.

Thus, Table 5.8 illustrates restrictions on advertising imposed on novel tobacco, nicotine or related products in different Member States. We find that ENDS were noted as being available for purchase in all Member States for which we received a response; however, only a few Member States appear to apply restrictions on the advertising of these products. This was also the case for herbal cigarettes where only Finland, Germany and Sweden apply some form of restriction on advertising to these products. It is noteworthy that some Member States impose restrictions on advertising through the internet generally and also on social networking and media sites for products such as ENDS, smokeless cigarettes and herbal cigarettes. These include: Finland, Germany, Latvia, Portugal, Slovenia, Spain, Sweden and the UK.

Table 5.8 Restrictions on advertising imposed on novel tobacco, nicotine or related products in EU Member States

| Product | At point of sale (display) | Over the internet generally | Over the internet on social networking and media sites | Other media (eg TV, magazines, billboards) |
|---|---|---|--|---|
| Electronic cigarettes, e-cigarette or ENDS | Denmark Finland Malta Portugal Sweden | Austria Denmark Estonia Finland Portugal Sweden | Finland Portugal Sweden | Austria Denmark Finland Malta Portugal Sweden |
| Smokeless cigarettes (non-battery operated) | Finland Sweden | Finland Sweden | Finland Sweden | Finland Sweden |
| Herbal cigarettes | Finland Germany Sweden | Finland Germany | Finland Germany | Finland Germany Sweden |
| Nicotine lollipops | | | | |
| Nicotine lozenges | | | | |
| Nicotine toothpick | | | | |
| Nicotine condoms | | | | |
| Herbal tobacco or herbal shisha for use in waterpipes | Finland Luxembourg Portugal Sweden | Austria Finland Portugal | Finland Portugal | Austria Finland Portugal Sweden |
| Nicotine wafers | | | | |
| Nicotine drink | | | | |
| Nicotine toothpaste | | | | |
| Nicotine cream | | | | |
| Nicotine spray | | | | |
| Nicotine lip balm | | | | |
| Tobacco tablets | Denmark Sweden | Denmark | | Denmark Sweden |
| Tobacco pellets, sticks and strips | Sweden | Sweden | Sweden | Sweden |

| Product | At point of sale (display) | Over the internet generally | Over the internet on social networking and media sites | Other media (eg TV, magazines, billboards) |
|--|----------------------------|-----------------------------|--|--|
| Tobacco water (tuihur/hidakphu) | | | | |
| Tobacco-infused drinks | | | | |
| Red tooth tobacco powder | | | | UK |
| Bajjar tooth powder | | | | UK |
| Gul (Gadakhu) tooth powder | | | | UK |
| Tobacco toothpaste (Quiwam) | UK | UK | UK | UK |
| Mishri tooth powder | | | | UK |
| Tobacco toothpaste (creamy snuff) | UK | UK | UK | UK |
| Tobacco-infused ingredients of cocktails | | | | |

SOURCE: RAND Europe survey, April-June 2011. Q15 Do any of the country-specific regulations applicable to these products require restrictions on advertising? Please select multiple boxes if applicable.

In Table 5.9, we provide an overview of regulatory measures aimed at controlling the sale of novel and emerging tobacco, nicotine or related products available for purchase in EU Member States. It is notable that considering that respondents from all Member States for which we received a response indicated ENDS are available for purchase in their country, only a few respondents stated there are restrictions on the purchase and sale of this product. Austria and Sweden appear to be the only two Member States that currently impose restrictions on the sale of herbal tobacco or herbal shisha for use in waterpipes. In addition, unsurprisingly perhaps, it would appear that the UK is the only country currently restricting the purchase and sale of tobacco products such as tobacco toothpaste and mishri tooth powder, the use of which is more prevalent in populations of Asian origin (India and Pakistan in particular).⁹³

Table 5.9 Regulatory measures aimed at controlling the sale of novel tobacco, nicotine or related products available for purchase in EU Member States

| Product | Registration or license for premises to sell them | Restriction of sales over the internet | Health and/or safety labelling | Age restriction |
|---|---|--|--------------------------------|----------------------------|
| Electronic cigarettes, e-cigarette or ENDS | Finland Portugal Sweden | Finland Portugal | Portugal UK | Finland Malta Sweden |
| Smokeless cigarettes (non-battery operated) | Finland Sweden | Finland | | Finland Sweden |
| Herbal cigarettes | Finland Germany | Finland Germany | Germany | Finland Latvia |
| Nicotine lollipops | | | | |
| Nicotine lozenges | | | | |
| Nicotine toothpick | | | | |
| Nicotine condoms | | | | |

| Product | Registration or license for premises to sell them | Restriction of sales over the internet | Health and/or safety labelling | Age restriction |
|--|---|--|--------------------------------|-------------------|
| Herbal tobacco or herbal shisha for use in waterpipes | Austria | Austria | Austria Sweden | Austria Sweden |
| Nicotine wafers | | | | |
| Nicotine drink | | | | |
| Nicotine toothpaste | | | | |
| Nicotine cream | | | | |
| Nicotine spray | | | | |
| Nicotine lip balm | | | | |
| Tobacco tablets | | Denmark | Denmark Sweden | Denmark Sweden |
| Tobacco pellets, sticks and strips | | | Sweden | Sweden |
| Tobacco water (tuihur/hidakphu) | | | | |
| Tobacco-infused drinks | | | | |
| Red tooth tobacco powder | UK | | UK | UK |
| Bajjar tooth powder | UK | | UK | UK |
| Gul (Gadakhu) tooth powder | UK | | UK | UK |
| Tobacco toothpaste (Quiwam) | UK | UK | UK | UK |
| Mishri tooth powder | UK | | UK | UK |
| Tobacco toothpaste (creamy snuff) | | | | |
| Tobacco-infused ingredients of cocktails | | | | |
| Other products indicated as available by Member State respondents | | | | |
| Gutkha | | UK | UK | UK |
| Khaini | | UK | UK | UK |
| "Seems to be a wide range of products in Asian grocers" | UK | | UK | UK |
| Snuff or Makla Bouhel | | UK | UK | UK |
| Snus (wet snuff loose and in portions) and tuggtobak (chewing tobacco) | Sweden | | Sweden | Sweden |

SOURCE: RAND Europe survey, April-June 2011. Q16 Do the regulations of these products require any of the following restrictions? Please select multiple boxes if applicable.

Table 5.10 provides an overview of the labelling requirements in place for the sale of novel tobacco, nicotine or related products in different EU Member States. Overall, very few of these products are required to feature labels. This is particularly interesting in the case of the two products that have been stated as being available in the majority of Member States for which we received a response: ENDS and herbal cigarettes.

Table 5.10 Labelling requirements for the sale of novel tobacco, nicotine or related products in EU Member States

| | Textual health warnings (eg "Smoking kills") | Pictorial health warnings | Information on services for smoking cessation | Safety warnings (eg on how to safely use the product) | Size of labels | Positioning of labels | Yield indications (nicotine, tar, etc) | Other |
|---|--|---------------------------|---|---|----------------|-----------------------|--|-------|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | | | | Portugal UK | | | | |
| Smokeless cigarettes (non-battery operated) | | | | | | | | |
| Herbal cigarettes | | | | | | | | |
| Nicotine lollipops | | | | | | | | |
| Nicotine lozenges | | | | | | | | |
| Nicotine toothpick | | | | | | | | |
| Nicotine condoms | | | | | | | | |
| Herbal tobacco or herbal shisha for use in waterpipes | Austria | | | | | | | |
| Nicotine wafers | | | | | | | | |
| Nicotine drink | | | | | | | | |
| Nicotine toothpaste | | | | | | | | |
| Nicotine cream | | | | | | | | |
| Nicotine spray | | | | | | | | |
| Nicotine lip balm | | | | | | | | |
| Tobacco tablets | Denmark | | | | Denmark | Denmark | | |
| Tobacco pellets, sticks and strips | | | | | | | | |
| Tobacco water (tuibur/hidakphu) | | | | | | | | |
| Tobacco-infused drinks | | | | | | | | |

| | Textual health warnings (eg "Smoking kills") | Pictorial health warnings | Information on services for smoking cessation | Safety warnings (eg on how to safely use the product) | Size of labels | Positioning of labels | Yield indications (nicotine, tar, etc) | Other |
|--|--|---------------------------|---|---|----------------|-----------------------|--|-------|
| Red tooth tobacco powder | | | | | | | | UK |
| Bajjar tooth powder | | | | | | | | UK |
| Gul (Gadakhu) tooth powder | | | | | | | | UK |
| Tobacco toothpaste (Quiwam) | UK | | | | UK | UK | | UK |
| Mishri tooth powder | | | | | | | | UK |
| Tobacco toothpaste (creamy snuff) | UK | | | | UK | UK | | UK |
| Tobacco-infused ingredients of cocktails | | | | | | | | |

SOURCE: RAND Europe survey, April-June 2011. Q17 Please specify the labelling requirements: Select multiple boxes if applicable

5.4.3 Age restrictions on the purchase of novel and emerging tobacco, nicotine or related products in EU Member States

To complement the information on restrictions on purchase as described in Table 5.9 above, we collected additional data specifically on whether EU Member States impose any age restrictions on the purchase of novel tobacco, nicotine or related products. This is further illustrated in Table 5.11. Respondents were given the option to indicate whether a given product was ‘not to be sold to under 16s’, ‘not to be sold to under 18s’ or ‘not to be sold to under 21s’, with a final ‘don’t know’ option.

As illustrated, most Member States that do impose an age limit on the purchase of novel and emerging tobacco, nicotine or related products specify that these cannot be sold to those under the age of 18 with the notable exception of Austria, where some products (herbal tobacco or herbal shisha for use in waterpipes) cannot be legally sold to those under the age of 16 years. With regard to ENDS that appear to be the most widely available product for purchase in all Member States for which we received a response (n=24), respondents from only two Member States stated there was regulation that specifies for this product not to be sold to under 18s; these are Finland and Malta, with Finland imposing a similar restriction on smokeless, non-battery operated cigarettes also.

Table 5.11 Age restrictions on the purchase of novel tobacco, nicotine or related products in EU Member States

| Product | Age limit |
|---|---|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | Not to be sold to under 18s in Finland and Malta |
| Smokeless cigarettes (non-battery operated) | Not to be sold to under 18s in Finland |
| Herbal cigarettes | Not to be sold to under 18s in Finland and Latvia |
| Nicotine lollipops | n/a |
| Nicotine lozenges | n/a |
| Nicotine toothpick | n/a |
| Nicotine condoms | n/a |
| Herbal tobacco or herbal shisha for use in waterpipes | Not to be sold to under 16s in Austria |
| Nicotine wafers | n/a |
| Nicotine drink | n/a |
| Nicotine toothpaste | n/a |
| Nicotine cream | n/a |
| Nicotine spray | n/a |
| Nicotine lip balm | n/a |
| Tobacco tablets | Not to be sold to under 18s in Denmark |
| Tobacco pellets, sticks and strips | n/a |
| Tobacco water (Tuibur/Hidakphu) | n/a |
| Tobacco-infused drinks | n/a |
| Red tooth tobacco powder | UK responded uncertain |

| Product | Age limit |
|--|---------------------------------------|
| Bajjar tooth powder | UK responded uncertain |
| Gul (Gadakhu) tooth powder | UK responded uncertain |
| Tobacco toothpaste (Quiwam) | Not to be sold to under 18s in the UK |
| Mishri tooth powder | UK responded uncertain |
| Tobacco toothpaste (creamy snuff) | Not to be sold to under 18s in the UK |
| Tobacco-infused ingredients of cocktails | n/a |
| Other products indicated by Member State respondents | |
| "Seems to be a wide range of products in Asian grocers" | UK responded uncertain |
| "Gutkha" | Not to be sold to under 18s in the UK |
| "Snus (wet snuff loose and in portions) and tuggtobak (chewing tobacco)" | Not to be sold to under 18s in Sweden |
| "Khaini" | Not to be sold to under 18s in the UK |
| "Snuff" | Not to be sold to under 18s in the UK |
| "Makla Bouhel" | Not to be sold to under 18s in the UK |

5.5 Summary

This chapter has described data collected from representatives of 24 out of 27 EU Member States on the availability, accessibility, usage and regulatory environment for novel and emerging tobacco, nicotine or related products in the European Union.

From the findings reported here, it would appear that the state of knowledge on the status of these products as it relates to their availability and regulation is uneven and patchy. This is in some ways unsurprising given that many of these products have only appeared on the European market recently, if at all in some countries, and that a range of them are still unregulated and/or only available through the internet for example. It should however be reiterated that the data presented here should be interpreted with caution, given the range of organisations surveyed, and the varying number of responses received from Member States. While a survey instrument such as the one employed here provides for the comparatively simple and standardised collection of information on a given topic area, it requires respondents to be knowledgeable in the field. Given the wide range of products covered in this survey, it was to be expected that the relevant information and knowledge base was unlikely to be held by a single organisation per Member State only. Indeed, respondents in a small subset of countries drew on a range of sources and organisations in order to address the questions set by the survey adequately. However, as this appears not to have been common practice across respondents, the quality of information provided is likely to vary considerably across Member States. Thus, for the future it will be important to follow up information collected in a second round, possibly involving key informant interviews, in order to validate and verify the data described here.

Against this background, a number of tentative observations can still be drawn. We find that there are wide ranging differences in the availability and regulation of novel tobacco, nicotine or related products among EU Member States. The single most commonly available product in EU Member States appears to be ENDS, or variations of this product,

followed by herbal cigarettes, and herbal tobacco or herbal shisha for use in waterpipes. Products such as nicotine drinks, nicotine toothpaste or tobacco-infused drinks were reported to be uncommon or not available at all. Products that are available are, principally, available for purchase from tobacco shops or, more frequently, the internet.

Although the overall evidence remains patchy, the regulatory environment for the products surveyed here is rather uneven across countries. Where novel tobacco, nicotine or related products are regulated, this most commonly applies to ENDS and their variants, herbal cigarettes, as well as herbal tobacco for use in waterpipes, with the latter two products most commonly regulated under existing tobacco legislation or, less frequently, food regulation. ENDS, where they are regulated, fall either under national tobacco regulation (Finland, Malta) and/or pharmaceutical regulation (Austria, Denmark, Estonia, Finland, Portugal, Sweden), and are currently regulated under REACH (Registration, Evaluation, Authorisation & restriction of CHemicals) in the UK.

Of the products surveyed, a small sample were classified as NRTs, such as ENDS and their variants, nicotine lozenges, nicotine spray and sticks, although classification as NRT of any of these products was limited to a subset of Member States only; nicotine lozenges are the most common product to being regulated in this way.

Where products are regulated, countries can issue a range of measures, such as imposing restrictions on advertising and the sale of products, and/or age restrictions. Where products are regulated under national tobacco legislation, restrictions similar to other tobacco products apply, including advertising restrictions, labelling and age restrictions, although it is noteworthy that of the products most frequently available in EU Member States, ENDS and its variants and herbal cigarettes appear to be subject to few restrictions as far as setting age limits and labelling is concerned.

This report has examined the availability, accessibility, use and regulatory environment for novel and emerging tobacco, nicotine or related products in EU Member States. Drawing on a range of methodological approaches involving a systematic evidence review, key informant interviews with representatives from industry, including retailers, and a survey of stakeholders at national governmental and non-governmental agencies, we find that the overall evidence on the availability and use of these products is patchy, with high variability in the quality of data that are available. This is particularly the case for data on prevalence of use; indeed, much of the evidence that is available tends to relate to a subset of smokeless tobacco products, typically chewing tobacco and snuff, with a small body of work evolving around the use of electronic nicotine delivery systems.^{24 57 94} Information on sales of these products is equally patchy, and published data by major market research companies such as Euromonitor International have tended, so far, to concentrate on chewing tobacco and snuff.²²

This apparent uncertainty around the availability and use of novel and emerging tobacco, nicotine or related products in the Europe Union is mirrored by the findings from the stakeholder survey conducted for this study. Keeping the limitations of the survey methodology in mind, it would appear that the state of knowledge among stakeholders at national agencies and/or NGOs on the status of these products as it relates to their availability and regulation is uneven and patchy.

However, based on the evidence compiled in this report we can draw some tentative conclusions. Thus, we find that there are wide ranging differences in the availability and regulation of novel tobacco, nicotine or related products among EU Member States. The single most commonly available product in EU Member States appear to be ENDS, or variations of this product, followed by herbal cigarettes, flavoured tobacco for use in waterpipes, and herbal tobacco or herbal shisha for use in waterpipes. Products such as nicotine drinks, nicotine toothpaste or tobacco-infused drinks were reported to be uncommon or not available at all. Products that are available are, principally, accessible through purchase from tobacco shops or, more frequently, the internet.

Although the overall evidence remains uncertain, the regulatory environment for the products surveyed here is rather uneven across countries. Where novel tobacco, nicotine or related products are regulated, this most commonly applies to ENDS and its variants, herbal cigarettes and/or herbal tobacco for use in waterpipes. With regard to herbal cigarettes it is noteworthy that respondents in eight out of 24 EU Member States that provided a response reported this product to be regulated in some form. However,

countries reporting that this is the case do not necessarily match those countries that were surveyed in an earlier study on the same topic area,³ although it is important to note that the survey question differed between the two studies while also undertaken at different points in time, so limiting comparability. However, the earlier study also covered the regulation of electronic nicotine delivery systems and with the exception of six countries (France, Germany, Hungary, Netherlands, Slovakia and Slovenia), reports on the regulation of this product are fairly comparable between the two surveys. While this inconsistency might reflect methodological limitations of representativeness of a given country of either study, it again highlights a continued uncertainty about the regulatory framework for these types of product across countries, although the level of uncertainty is likely to vary among product categories.

Against this background it would appear that it will be important to follow up on the findings of the survey presented here and in earlier reports³ in order to better understand the extent to which the apparent uncertainty about the availability and regulation of novel and emerging tobacco, nicotine and related products reflects, among stakeholders, a lack of knowledge, because the product in question is not regarded as a policy issue or there is lack of corresponding data in EU Member States, or both. For a fuller understanding of emerging patterns and trends, it would therefore seem important to build on the ongoing exchange already established at the EU level within the Regulatory Committee meetings to develop further a mechanism for the systematic monitoring and surveillance on the availability, accessibility, usage and regulation of novel and emerging tobacco, nicotine and related products that enables collecting relevant data at national level across the EU. The need for responsive monitoring and surveillance has been raised as an important public health issue in the US in relation to newly emerging potential reduced exposure products (PREPs), encompassing a range of products including ENDS and smokeless tobacco. Specifically, O'Connor et al. (2009) emphasised the need for accurate and timely data that would provide insights into when, where, how and types of novel and emerging products that have been introduced, alongside information on how the products are being used, in order to enable public health agencies to identify trends and to respond to new developments in products that may impact on population health.⁹⁵ Similar issues have also been raised within the WHO FCTC in an attempt, within Articles 9 and 10 of the FCTC on the regulation of the contents of tobacco products and of tobacco product disclosures, to develop guidelines for the systematic reporting and disclosure of contents and product characteristics to cover all tobacco containing products.⁹⁶

One potential suggestion to improve the current uncertainty in EU Member States on the availability and use of novel and emerging products may be to establish a register of retail outlets selling any tobacco and/or nicotine products at regional or national level so as to enable monitoring the extent to which these adhere to national legislation on, for example, advertisement, or sales to minors, where relevant legislation has been implemented (Chapter 5). To what extent such regulation would enable monitoring online retail remains difficult to assess. Even where age restrictions on purchase are being stated as formal policy, possession of a credit card is frequently seen as the only indicator for manufacturers and retailers of adult status of their customers (Chapter 4). The US, in its 2009 Prevent All Cigarette Trafficking Act (PACT), in force from June 2010, has banned the shipment of tobacco products (cigarettes and smokeless tobacco products) using the

US postal service.⁸³ Although products can still be shipped using alternative routes through international carriers such as UPS, the recipient will have to be ID-checked on arrival of the product. This has restricted the ability of online retailers to sell smokeless tobacco products, including chewing tobacco, snuff, and other smokeless tobacco products such as dissolvable tobacco. However, ENDS remain relatively freely available.

Against this background, building further on the ongoing exchange established at the EU level within the Regulatory Commission on monitoring and surveillance noted above would permit exchange of data and information among Member States on the availability of novel and emerging tobacco, nicotine and related products. This might also include reporting on ongoing research, so as to optimise scarce resources or indeed stimulate cross-country efforts for the systematic collection of data on the availability and use of these products across the union, along with information on experiences of regulatory concerns and options. It may be noteworthy, in this context, that a recent consultation by the UK MHRA on the regulation of nicotine-containing products decided to not ban these products, for the time being, as it would have meant taking a product off the market that, overall, may be considered less harmful than cigarettes, which, while regulated, remain widely available and easily accessible, despite the much greater harm they cause.⁸⁶ However, as noted earlier, acknowledging the need for further information to be collected to better understand the use of existing nicotine-containing products in the marketplace and the potential impact of the regulation on public health outcomes, a final decision on the regulation of these products is foreseen for spring 2013. At the same time, the ongoing discussion in the UK highlights the potential role that could be played, at the EU level, by the European Medicines Agency. Furthermore, in monitoring and regulating novel and emerging tobacco, nicotine or related products, the spectrum of harm caused by cigarettes (which despite being the most harmful are freely available and easily accessible) to pharmacological nicotine (which currently has the best safety record and is highly regulated) should be borne in mind. In this respect, comparing the safety of such products with cigarettes would form a key part of any evaluation.

REFERENCES

Reference list

1. Scoggins A, de Vries H, Conklin A, Hatziandreu E. Analysis to Support the Impact Assessment of the Commission's Smoke-free Initiatives. Santa Monica: RAND Corporation, 2009.
2. Smokefree Partnership. Annual Report 2009. Brussels: Smokefree Partnership, 2009.
3. Tiessen J, Hunt P, Celia C, Fazekas M, de Vries H, Staetsky L, et al. Assessing the impacts of revising the Tobacco Products Directive: Study to support a DG SANCO impact assessment. Santa Monica: RAND Corporation, 2011.
4. WHO Framework Convention on Tobacco Control. Parties to the WHO Framework Convention on Tobacco Control. [Online] Available at http://www.who.int/fctc/signatories_parties/en/index.html (accessed 6 May 2011).
5. The European Parliament and the European Council. Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, *OJ L*, 18 July 2001, 194: 26–35.
6. U.S. Food and Drug Administration. Letter to industry on dissolvable smokeless tobacco products (Star Scientific, Inc). [Online] Available at: <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm199711.htm> (accessed 1 November 2010).
7. U.S. Food and Drug Administration. Tobacco products. [Online] Available at <http://www.fda.gov/tobaccoproducts/default.htm> (accessed 1 November 2010).
8. Scientific Committee on Emerging and Newly Identified Health Risks. Health effects of smokeless tobacco products. Brussels: European Commission, 2008.
9. McKee M, Gilmore A. Commentary: smokeless tobacco: seeing the whole picture. *Int J Epidemiol* 2007;36:805-808.
10. e-cig.bg. Electronic cigarettes. [Online] Available at <http://e-cig.bg/> (accessed 30 March 2011).
11. Ecigarette-France. Accueil. [Online] Available at <http://www.ecigarette-france.com/> (accessed 15 April 2011)
12. KYF. Boutique cigarette électronique KYF. [Online] Available at <http://www.e-kyf.com/> (accessed 15 April 2011).
13. Narguile.info. L'achat : les shops. [Online] Available at <http://www.narguile.info/shops.php#liste> (accessed 15 April 2011).

14. Shisha-World.com. Herzlich Willkommen bei shisha-world.com. [Online] Available at <http://www.shisha-world.com/> (accessed 15 April 2011).
15. Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac. Smokeless tobacco glossary. [Online] Available at http://www.coresta.org/Study_Groups/CSTS%20Smokeless%20Tobacco%20Glossary.pdf (accessed 8 April 2011).
16. World Tobacco. Tobacco Journal International & World Tobacco have merged. [Online] Available at <http://www.worldtobacco.co.uk/> (accessed 27 June 2011).
17. Tobacco Journal International, World Tobacco. Home. [Online] Available at http://www.tobaccojournal.com/Home.21127.0.html?&no_cache=1 (accessed 23 February 2011).
18. Tobacco Reporter. Home. [Online] Available at <http://www.tobaccoreporter.com/> (accessed 23 February 2011).
19. Euromonitor International. Global tobacco: Survival strategies for a savage market. November 2008. London/Chicago/Singapore/Shanghai/Vilnius/Dubai: Euromonitor International, 2008.
20. Euromonitor International. Global tobacco: New product developments - regional and country overview. September 2009. London/Chicago/Singapore/Shanghai/Vilnius/Dubai: Euromonitor International, 2009.
21. Euromonitor International. Global tobacco: New product developments - creativity in adversity. September 2009. London/Chicago/Singapore/Shanghai/Vilnius/Dubai: Euromonitor International, 2009.
22. Euromonitor International. Smokeless tobacco - Is it the future of the industry? April 2010. London/Chicago/Singapore/Shanghai/Vilnius/Dubai: Euromonitor International, 2010.
23. Euromonitor International. Smokeless tobacco. [Online] Available at <http://www.euromonitor.com/search?txtSearch=smokeless+tobacco> (accessed 16 June 2011).
24. Ayers J, Ribisi K, Brownstein J. Tracking the rise in popularity of electronic nicotine delivery systems (electronic cigarettes) using search query surveillance. *Am J Prevent Med* 2011;40:448-453.
25. Longman L, Pritchard, McNeill A, Csikar J, Croucher R. Accessibility of chewing tobacco products in England. *J Public Health* 2010;32:372-378.
26. Warnakulasuriya S. Areca nut use following migration and its consequences. *Addiction Biology* 2002;7:127-132.
27. TNS Opinion & Social. Tobacco. Special Eurobarometer 332. Brussels: European Commission, 2010.
28. Richter P, Caraballo R, Pederson L, Gupta N. Exploring use of nontraditional tobacco products through focus groups with young adult smokers, 2002. *Public Health Res Pract Policy* 2008;5: A87.
29. Martinasek M, McDermott R, Martini L. Waterpipe (hookah) tobacco smoking among youth. *Curr Probl Pediatr Adolesc Health Care* 2011;41:34-57.
30. Ward K, van der Weg M, Relyea G, Debon M, Klesges R. Waterpipe smoking among American military recruits. *Prev Med* 2006;43:92-97.
31. Noonan D and Kulbok PA. New tobacco trends: waterpipe (hookah) smoking and implications for healthcare providers. *J Am Acad Nurse Pract* 2009;21:258-260.

32. Everyonedoesit.com. Farmers Honeyblend - Herbal Blend. [Online] Available at http://www.everyonedoesit.com/online_headshop/Farmers_Honeyblend__Herbal_Smoking_Blend.cfm?iProductID=3789 (accessed 10 May 2011).
33. Honeyrose. Honeyrose - Sigarette alle Erbe. [Online] Available at <http://www.mellisrose.it/shop/> (accessed 10 May 2011).
34. Honeyrose Products Ltd. How to buy. Worldwide distributors. [Online] Available at <http://www.honeyrose.co.uk/dist2.html> (accessed 10 May 2011).
35. Blank M, Cobb C, Kilgaleen B, Austin J, Weaver M, et al. Acute effects of waterpipe tobacco smoking: A double-blind, placebo-controlled trial. *Drug Alcohol Depend* 2011;116:102-109.
36. Knishkowsky B, Amitai Y. Water-pipe (Narghile) smoking: An emerging health risk behavior. *Pediatrics* 2005;116:e113-119.
37. Eurobarometer. Tobacco. Brussels: European Commission, 2010.
38. Star Scientific Inc. Reducing harm at every level. [Online] Available at <http://www.starscientific.com/> (accessed 10 May 2011).
39. Goran Pharma Ltd. <http://www.creampaste.com/tobacco.htm>.
40. Asha Industries. <http://www.ipcosnuff.com>.
41. Niche Tobacco Products Directory. Khaini. [Online] Available at <http://www.ntpd.lacors.gov.uk/lacors/core/page.do?pageId=156946> (accessed 10 May 2011).
42. Hickman N, Klonoff E, Landrine H, Kashima K, Parekh B, Fernandez S, et al. Preliminary investigation of the advertising and availability of PREPs, the new "safe" tobacco products. *J Behav Med* 2004;27:413-424.
43. McNeill A, Bedi R, Islam S, Alkhatib M, West R. Levels of toxins in oral tobacco products in the UK. *Tobacco Control* 2006;15:64-67.
44. Prignot J, Sasco A, Poulet E, Gupta P, Aditama T. Alternative forms of tobacco use. *Int J Tuberc Lung Dis* 2008;12.:718-727.
45. Flora M, Mascie-Taylor C, Rahman M. Gender and locality differences in tobacco prevalence among adult Bangladeshis. *Tobacco Control* 2009;18:445-450
46. Daniel A, Nagaraj K, Kamath R. Prevalence and determinants of tobacco use in a highly literate rural community in southern India. *Natl Med J India* 2008;21:163-165.
47. Gupta P, Warnakulasuriya S. Global epidemiology of areca nut usage. *Addict Biol* 2002;7:77-83.
48. Fagerström K. The nicotine market: An attempt to estimate the nicotine intake from various sources and the total nicotine consumption in some countries. *Nicotine & Tobacco Research* 2005;7:343-350.
49. No Tobacco. Net. [Online] Available at <http://www.notobacco.net/Blog/?tag=ehcss> (accessed 14 April 2011).
50. Smokefree Innotec. General Information. [Online] Available at <http://www.smokefreeinnotec.com/product/general-information> (accessed 5 June 2011).
51. Smokefree Innotec. Smokefree's European Patent 08738110.9 issued and published. Market Wire, 15 June 2011. [Online] Available at <http://www.marketwire.com/press-release/smokefree-european-patent-087381109-issued-and-published-pinksheets-sfio-1527371.htm> (accessed 17 June 2011).

52. Similar. What are Similar Smokeless Cigarettes? [Online] Available at <http://www.similarshop.eu/commerce/smokelesscigarettes/company/smokeless.jsf> (accessed 10 June 2011).
53. Electronic Cigarettes Reviews. Electronic cigarette reviews. [Online] Available at <http://www.electroniccigarettesreviews.net/?d=google> (accessed 14 April 2011).
54. Electronic Cigarette Spot. Makers/Brands. [Online] Available at <http://electroniccigarettespot.com/electronic-cigarette-brands/brand-index> (accessed 14 April 2011).
55. U.S. Food and Drug Administration. Summary of results: laboratory Analysis of electronic cigarettes conducted by FDA. [Online] Available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm> (accessed 15 March 2011).
56. Etter J. Electronic cigarettes: a survey of users. *BMC Public Health* 2010;10:231.
57. Etter J, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011;106:2017-2028.
58. The Compounder. Nicotine lollipops FAQ. [Online] Available at <http://www.thecompounder.com/your-health/quit-smoking/nicotine-lollipops/nicotine-lollipops-faq> (accessed 10 May 2011).
59. Western Iowa Compounding Solutions. Nicostop Lollipops. [Online] Available at http://www.getacompound.com/compoundinfo/nicotine_lollipops.htm (accessed 10 May 2011).
60. Tobacco Products. Lip Balm/suckers. [Online] Available at http://tobaccoproducts.org/index.php/Lip_Balm/suckers (accessed 10 May 2011).
61. Innovaro Pharmalicensing. Jaleva's 'Nicofix', a transbuccal nicotine replacement therapy product, achieves outstanding test results. Available at http://pharmalicensing.com/public/press/view/1290616750_4ced3faebc00d/jaleva-s-nicofix-a-transbuccal-nicotine-replacement-therapy-product-achieves-outstanding-test-results (accessed 14 April 2011).
62. Nicovar. Home. [Online] Available at <http://www.nicovar.com/> (accessed 14 April 2011).
63. Energy Drink. Energy Drink. [Online] Available at <http://www.indiamart.com/jmjgroup/energy-drinks.html> (accessed 14 April 2011).
64. Weiss S, Smith-Simone S. Consumer and health literacy: The need to better design tobacco-cessation product packaging, labels, and inserts. *Am J Prevent Med* 2010;38(3S):S403-S413.
65. McRobbie H, Thornley S, Bullen C, Lin R, Senior H, Laugesen M, et al. A randomized trial of the effects of two novel nicotine replacement therapies on tobacco withdrawal symptoms and user satisfaction. *Addiction* 2010;105:1290-1298.
66. Niconovum. Zonnice Mouth Spray. [Online] Available at <http://www.niconovum.se/Products.aspx?id=2462985310837672489> (accessed 13 April 2011).
67. Stop Smoking Foundation. Commit lozenges review. [Online] Available at <http://www.stopsmoking.net/commit-lozenges.html> (accessed 14 April 2011).

68. GlaxoSmithKline. NiQuitin Lozenge Original. [Online] Available at <http://www.gskdirect.co.uk/products/niquitin-lozenge-original.html> (accessed 15 July 2011).
69. One Click Pharmacy. NiQuitin CQ 2mg Lozenges x 72. [Online] Available at <http://www.oneclickpharmacy.co.uk/medicines-smoking-cessation-lozenges-niquitin-lozenges-p-36182.html?offerdone=1> (accessed 15 July 2011).
70. Zonnic. Här hittar du våra produkter. [Online] Available at <http://zonnic.se/aaterfoersaeljare.aspx> (accessed 13 April 2011).
71. Hasenfratz M, Bättig K. Nicotine absorption and the subjective and physiologic effects of nicotine toothpicks. *Clin Pharmacol Ther* 1991;50:456-461.
72. Gilmore A. Tobacco industry strategies to undermine public health policies in Europe. *European Conference on Tobacco or Health*. Amsterdam, 2011.
73. Anonymous. Let the consumer decide. *Tobacco Journal International*; June 2009:80.
74. Nicoventures. Nicoventures. [Online] Available at <http://www.nicoventures.co.uk/> (accessed 9 May 2011).
75. Cookson C. BAT to market nicotine without the smokes. *Financial Times*, 2 April 2011. [Online] Available at <http://www.ft.com/cms/s/0/d9f951ae-5eeb-11e0-a2d7-00144feab49a,s01=1.html#axzz1QVLtsDZb> (accessed 10 May 2011).
76. Jacobs R. Pursuit of a safer cigarette takes pace. *Financial Times*, 1 June 2011 [Online] Available at <http://www.ft.com/cms/s/0/4ceee0e6-8c7a-11e0-883f-00144feab49a.html> (accessed 10 June 2011).
77. Anonymous. Still in the middle of a big trend. *Tobacco Journal International*; June 2009:90.
78. Lock K, Adams E, Pilkington P, Duckett K, Gilmore A, Marston C. Evaluating social and behavioural impacts of English smokefree legislation in different ethnic and age groups: implications for reducing smoking-related health inequalities. *Tobacco Control* 2010;19:391-397.
79. Anonymous. New playing fields for flavours. *Tobacco Journal International*; June 2009:87.
80. Anonymous. Small is beautiful. *Tobacco Journal International*; September 2009.
81. Oliver Twist. About us. [Online] Available at <http://www.oliver-twist.dk/Webnodes/en/Web/Public/Profil/About+us> (accessed 10 May 2011).
82. Machir S. Star Scientific receives notices from FDA: Ariva-BDL(TM) and Stonewall-BDL(TM) not subject to regulation under FDC Act Chapter IX. Glen Allen, Virginia. 23 March 2011. [Online] Available at <http://www.starscientific.com/news/star-scientific-receives-notice-from-fda-ariva-bdltm-and-stonewall-bdltm-not-subject-to-regulation-under-fdc-act-chapter-ix/> (accessed 23 May 2011).
83. 111th Congress. Prevent All Cigarette Trafficking Act of 2009, Public Law 111-154, 124 Stat. 1087 (2010). [Online] Available at: <http://www.gpo.gov/fdsys/pkg/PLAW-111publ154/html/PLAW-111publ154.htm> (accessed 27 June 2011).
84. Kidwell H. When is a cigarette not a tobacco product? *Tobacco Journal International*; June 2009.
85. Peterson M. Electronic cigarettes to be regulated as tobacco products, U.S. FDA says. *Bloomberg Online*, April 25 2011. [Online] Available at

- <http://www.bloomberg.com/news/2011-04-25/fda-to-regulate-electronic-cigarettes-as-tobacco-products-1-.html> (accessed 21 June 2011).
86. Medicines and Healthcare products Regulatory Agency. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). 1 February 2010. [Online] Available at <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617> (accessed 11 May 2011).
87. The Electronic Cigarette Company. Welcome. [Online] Available at <http://www.theelectroniccigarette.co.uk/> (accessed 15 June 2011).
88. The Electronic Cigarette Company. Are you after the personal touch? [Online] Available at <http://www.theelectroniccigarette.co.uk/news/2011/june/are-you-after-the-personal-touch.html> (accessed 15 June 2011).
89. Smokefree Innotec. S.W.O.T. Analysis. [Online] Available at <http://www.smokefreeinnotec.com/marketing/s-w-o-t-analysis> (accessed 7 June 2011).
90. Anderson S, Ling P. And they told two friends...and so on": RJ Reynolds' viral marketing of Eclipse and its potential to mislead the public. *Tobacco Control* 2008;17:222-229.
91. The Smokeless Cigarette Company. Sales and marketing presentation (unpublished). 2010.
92. White R. Several carriers show interest in smokeless cigarettes. PAX International, 26 February 2010. [Online] Available at http://www.paxintl.com/Paxenews/paxenews_feb2610/paxnews_feb2610_airline10.html (accessed 17 June 2011).
93. Niche Tobacco Products Directory. Welcome to the NTPD - the directory of niche tobacco products. [Online] Available at <http://www.ntpd.lacors.gov.uk/lacors/core/page.do?pageId=1> (accessed 28 February 2011).
94. Etter J. Electronic cigarettes: a survey of users. *BMC Public Health* 2009;10:231.
95. O'Connor R, Cummings K, Rees V, Connolly G, Norton K, Swenor D, et al. Surveillance methods for identifying, characterizing, and monitoring tobacco products: potential reduced exposure products as an example. *Cancer Epidemiol Biomarkers Prev* 2009;18:3334-3348.
96. WHO Framework Convention on Tobacco Control. Partial guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures). [Online] Available at <http://www.who.int/fctc/guidelines/Decisions9and10.pdf> (accessed 15 July 2011).

APPENDICES

Appendix A Evidence review stage I

This section presents an overview of the search strategy carried out to identify the range of novel and emerging tobacco and nicotine products that are or may be available on European markets.

Bibliographical databases

We searched the PubMed bibliographic database of biomedical studies. We used a very broad range of search terms in order to capture novel tobacco and nicotine products. Using these terms, the overall search yielded around 50 studies that were considered of relevance for the present work (Table A.1).

Table A.1 Search terms and records identified, PubMed database

| No. | Search term(s) | # records | # considered as of relevance |
|-----|--|-----------|---|
| 1 | new tobacco products AND prevalence | 180 | 43 (<i>including marketing related articles</i>) |
| 2 | novel tobacco products AND prevalence | 7 | (<i>captured under #1</i>) |
| 3 | new nicotine products AND prevalence AND Europe | 5 | (<i>captured under #1</i>) |
| 4 | novel nicotine products AND prevalence AND Europe | 0 | |
| 5 | emerging tobacco products AND prevalence AND Europe | 2 | 1 (<i>duplicate from search #1</i>) |
| 6 | emerging nicotine products AND prevalence AND Europe | 0 | |
| 7 | new trends AND tobacco | 2 | 0 (<i>addressing prevention</i>) |
| 8 | new trends AND nicotine | 2 | 0 (<i>addressing nutrition and insecticides</i>) |
| 9 | merging AND products AND tobacco | 31 | 1 (<i>mostly harm reduction and smoking cessation-focused</i>) |
| 10 | emerging AND products AND nicotine | 13 | 0 (<i>pollution/environmental contaminants, smoking cessation or harm reduction</i>) |
| 11 | alternative AND products AND tobacco AND Europe | 14 | 0 (<i>several on snus (excluded) and health impacts of smokeless tobacco</i>) |
| 12 | alternative AND products AND nicotine AND Europe | 6 | (<i>duplicates of searches #1–11</i>) |
| 13 | substitute AND tobacco AND products | 23 | <i>many on public health implications of smokeless tobacco, one reference to nicotine nasal spray, one reference to nicotine toothpicks</i> |
| 14 | substitute AND nicotine AND tobacco AND products | 11 | 3 (<i>plus duplicates; others addressing harm reduction and smoking cessation</i>) |

SOURCE: Targeted journals and newsletters

We conducted a targeted search of one scientific journal (*Tobacco Control*) and the monthly newsletter of Action on Smoking and Health (ASH) based in the UK. Both sources were searched for the period 1992 (*Tobacco Control*) and 1999 (ASH newsletter) to the present. To identify information on novel tobacco and nicotine products, we kept the search fairly broad, focusing on new and emerging trends rather than specific products, so yielding some 20 studies and pointers which we considered relevant for the present work (Table A.2).

Table A.2 Search terms and records identified, targeted journals and newsletters

| Source | Search term(s) | # records | # considered of relevance |
|-----------------------------|-----------------------|-----------|----------------------------------|
| <i>Tobacco Control</i> | new trends | 4 | 1 |
| | emerging and products | 167 | 12 (<i>incl. on marketing</i>) |
| ASH Newsletter (England) | emerging | 82 | 1 |
| | new products | 30 | 4 |
| | novel | 62 | 2 |

Governmental, inter- and non-governmental organisations

We searched the website of the European Medicines Agency (EMA) and the US-based FDA. These searches did not yield any material considered of relevance for the present work, despite the large number of records containing the range of search terms considered (Table A.3). This was mainly because products are mentioned in relation to their approval as smoking cessation aids and/or the regulation of smokeless tobacco products in the US.

Table A.3 Search terms and records identified, (non-)governmental organisations

| Source | Search term(s) | # records | # considered as of relevance |
|-------------------|--------------------------|-----------|------------------------------|
| EMA | novel tobacco products | 39 | 0 |
| | novel nicotine products | 18 | 0 |
| | nicotine condom | 0 | 0 |
| FDA (US) | smokeless tobacco | 1,200 | 0 |
| | smokeless | 516 | 0 |
| | new tobacco products | 15,100 | 0 |
| | new tobacco product | 30 | 0 |
| | nicotine | 1,820 | 0 |
| | herbal cigarette | 2 | 0 |
| | herbal cigarettes | 1 | 0 |
| | electronic cigarettes | 112 | 0 |
| | British American tobacco | 532 | 0 |
| | imperial tobacco | 2 | 0 |
| | Philip Morris | 110 | 0 |
| Reynolds American | 6 | 0 | |

Industry sources

We searched the websites of European and global tobacco manufacturers and retailers (Table A.4) to inform the development of a potential typology or classification system of products. We will revisit these sources once the range of products to be examined in more detail has been agreed with the Commission (eg several international tobacco

manufacturers are producing their own brand of *snus*, which is currently excluded from our definition of novel tobacco and nicotine products).

Table A.4 Sources of trade information on tobacco and nicotine products

| Geographic coverage | Tobacco manufacturers and retailers |
|---------------------|--|
| European | <ul style="list-style-type: none"> • Confederation of European Community Cigarette Manufacturers • European Cigar Manufacturers Association • European Rolling Paper Association • European Smokeless Tobacco Council • European Smoking Tobacco Association • Swedish Match Cigars • European Confederation of Tobacco Retailers • European Tobacco Wholesalers Association • European Vending Association |
| Global/non-European | <ul style="list-style-type: none"> • British American Tobacco (UK-based) • RJ Reynolds Tobacco Company • Japan Tobacco International • Imperial Tobacco Group • Altadis • Philip Morris International (PMI) • China National Tobacco Company • Other state-owned tobacco companies (eg in Taiwan, South Korea and Thailand) |

In addition, we (hand) searched relevant trade journals for novel products:

- *World Tobacco* (2009): no records of relevance identified
- *Tobacco Journal International* (2009–2010): identified four records considered relevant
- *Tobacco Journal International* (online; ‘Products and Trends’ section): identified four records considered relevant
- *Tobacco Reporter* (online): identified three products for inclusion in the compendium.

Other sources

(a) Euromonitor International market research reports

- ‘Global tobacco: survival strategies for a savage market’ (Nov 2008)¹⁹
- ‘Global tobacco: new product developments – regional and country overview’ (Sep 2009)²⁰
- ‘Global tobacco: new product developments – creativity in adversity’ (Dec 2009)²¹
- ‘Smokeless tobacco – Is it the future of the industry?’ (Apr 2010).²²

(b) The Niche Tobacco Products Directory (NTPD)

An online directory that provides detailed information about a range of niche tobacco products, specifically smokeless products and shisha. It has been developed and is managed by a partnership comprising LACORS and Trading Standards Services, specifically the London Regional Trading Standards Group, South West Regional Trading Standards Group and Trading Standards North West, England, UK.⁹³

Appendix B Key informant interview topic guide

- (i) Introduction: general information about company, history, etc.
- (ii) (For retailers) From where do you source your products?
- (iii) Distribution outlets (eg online only)? Some countries more than others? Volumes sold?
- (iv) Intended customer demographics?
- (v) How do you ensure your products are not sold to minors?
- (vi) How do you compete with cigarette companies for customers?
- (vii) How do you compete with other distributors of the same product?
- (viii) What sets this product apart from other nicotine products?
- (ix) What do you see as the obstacles and opportunities for your company?
- (x) How do you see the future of the company and [relevant product] market in Europe? Do you foresee it expanding, or as more of niche market?
- (xi) We would be interested in speaking with producers (as well as retailers) to get a better idea of sales volumes and destinations. Would you possibly be able to provide us with contact information for your suppliers?

Appendix C Abbreviated survey addressed to medicines agencies

Dear Madam or Sir,

We recently invited you to participate in a survey about novel and emerging tobacco and nicotine products in the European Union to inform the regulatory environment of these products.

We understand that many of the products we are interested in may not be within the remit of your agency. We would however be very interested indeed to collect information on whether any of the products are authorised as Nicotine Replacement Therapies (NRT) in your country. We therefore kindly ask you to look at the list of products displayed below and provide information whether these are authorised as NRT.

We appreciate that you have a very busy schedule but would be very grateful indeed if you could spare some 15 minutes to respond, to the best of your knowledge, until Friday, June 17th 2011.

Please accept our apologies for cross-posting if you have already completed the full online survey at <http://www.keysurvey.co.uk/survey/362929/5d17/>.

Thank you very much for supporting this research,

Ellen Nolte

Which of the following tobacco or nicotine products are authorised as Nicotine Replacement Therapies (NRTs) in your country? Please put a cross (“x”) in the relevant box.

Country:

| | Authorised as a NRT | NOT Authorised as a NRT | Don't know |
|---|---------------------|-------------------------|------------|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | | | |
| Smokeless cigarettes (non-battery operated) | | | |
| Herbal cigarettes | | | |
| Nicotine lollipops | | | |
| Nicotine lozenges | | | |
| Nicotine toothpick | | | |
| Nicotine condoms | | | |
| Flavoured tobacco for use in water pipes | | | |
| Herbal tobacco or herbal shisha for use in water pipes | | | |
| Other nicotine or tobacco products for use in water pipes | | | |
| Nicotine wafers | | | |
| Nicotine drink | | | |
| Nicotine toothpaste | | | |
| Nicotine cream | | | |
| Nicotine spray | | | |
| Nicotine lip balm | | | |
| Tobacco tablets | | | |
| Tobacco pellets, sticks and strips | | | |
| Tobacco water (tuibur/hidakphu) | | | |
| Tobacco-infused drinks | | | |
| Red tooth tobacco powder | | | |
| Bajjar tooth powder | | | |
| Gul (Gadakhu) tooth powder | | | |
| Tobacco toothpaste (Quiwam) | | | |
| Mishri tooth powder | | | |
| Tobacco toothpaste (creamy snuff) | | | |
| Tobacco-infused ingredients of cocktails | | | |
| Other novel tobacco or nicotine product(s) (i.e. not cigarettes, pipes or rolled tobacco) | | | |

Appendix D Regulation of novel tobacco and nicotine products by type of regulation

Table A.5 Coverage of novel products under national tobacco regulation

| Product | Coverage of national tobacco regulation |
|---|--|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | Finland: Uncertain – either covered partially (advertising, marketing and sales promotion) or fully under Tobacco Act 693/1976 Malta: Covered fully under Tobacco Smoking Control Act |
| Smokeless cigarettes (non-battery operated) | Finland: Uncertain – either covered partially (advertising, marketing and sales promotion) or fully under Tobacco Act 693/1976 |
| Herbal cigarettes | Finland: Covered partially (advertising, marketing, sales promotion and nicotine content) under Tobacco Act 693/1976 |
| Nicotine lollipops | n.a. |
| Nicotine lozenges | n.a. |
| Nicotine toothpick | n.a. |
| Nicotine condoms | n.a. |
| Herbal tobacco or herbal shisha for use in waterpipes | Covered fully in Portugal (Law 37/2007 of 14 August). Covered partially (advertising) in Finland |
| Nicotine wafers | n.a. |
| Nicotine drink | n.a. |
| Nicotine toothpaste | n.a. |
| Nicotine cream | n.a. |
| Nicotine spray | n.a. |
| Nicotine lip balm | n.a. |
| Tobacco tablets | Covered fully in Denmark (LOV nr. 375 af 6. juni 2002 om fremstilling, presentation og salg af tobaksvarer) |
| Tobacco pellets, sticks and strips | Covered fully in Sweden (Tobakslagen (1993:581)) |
| Tobacco water (tuibur/hidakphu) | n.a. |
| Tobacco-infused drinks | n.a. |
| Red tooth tobacco powder | Covered partially in UK (a range of UK regulations) |
| Bajjar tooth powder | Covered partially in UK (a range of UK regulations) |
| Gul (Gadaku) tooth powder | Covered partially in UK (a range of UK regulations) |

| Product | Coverage of national tobacco regulation |
|---|--|
| Tobacco toothpaste (Quiwam) | Uncertain whether covered fully or partially in the UK (Consumer Protection Act 1987 (CPA); Tobacco Products (Manufacture, Presentation & Sale) Safety Regulations 2002) |
| Mishri tooth powder | Covered partially in UK (a range of UK regulations) |
| Tobacco toothpaste (creamy snuff) | Uncertain whether covered fully or partially in the UK (Consumer Protection Act 1987 (CPA); Tobacco Products (Manufacture, Presentation & Sale) Safety Regulations 2002) |
| Tobacco-infused ingredients of cocktails | n.a. |
| Other products indicated as available by respondents in their Member State | |
| "Seems to be a wide range of products in Asian grocers" | Covered partially in UK (a range of UK regulations) |
| "Gutkha" | Covered fully the UK (Consumer Protection Act 1987 (CPA); Tobacco Products (Manufacture, Presentation & Sale) Safety Regulations 2002) |
| "Khaini" | Covered fully in the UK (Consumer Protection Act 1987 (CPA); Tobacco Products (Manufacture, Presentation & Sale) Safety Regulations 2002) |
| "Makla Bouhel" | Covered fully in the UK (Consumer Protection Act 1987 (CPA); Tobacco Products (Manufacture, Presentation & Sale) Safety Regulations 2002; Tobacco Products for Oral Use (Safety) Regulations 1992) |

Table A.6 Coverage of novel products under national food regulation

| Product | Coverage of pharmaceutical regulation |
|---|---|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | n.a. |
| Smokeless cigarettes (non-battery operated) | n.a. |
| Herbal cigarettes | Covered partially (content) in Finland (Foodstuff Law 13.1.2006/23) |
| Nicotine lollipops | n.a. |
| Nicotine lozenges | n.a. |
| Nicotine toothpick | n.a. |
| Nicotine condoms | n.a. |
| Herbal tobacco or herbal shisha for use in waterpipes | Covered partially (list of ingredients) in the UK (Food Labelling Regulations) Uncertain whether covered in Finland |
| Nicotine wafers | n.a. |
| Nicotine drink | n.a. |
| Nicotine toothpaste | n.a. |
| Nicotine cream | n.a. |
| Nicotine spray | n.a. |
| Nicotine lip balm | n.a. |
| Tobacco tablets | n.a. |
| Tobacco pellets, sticks and strips | n.a. |
| Tobacco water (tuibur/hidakphu) | n.a. |
| Tobacco-infused drinks | n.a. |
| Red tooth tobacco powder | n.a. |
| Bajjar tooth powder | n.a. |
| Gul (Gadakhu) tooth powder | n.a. |
| Tobacco toothpaste (Quiwam) | n.a. |
| Mishri tooth powder | n.a. |
| Tobacco toothpaste (creamy snuff) | n.a. |
| Tobacco-infused ingredients of cocktails | n.a. |
| 'Örtsnus (herbal <i>snus</i>)' | Covered partially (the production process of <i>snus</i> and tuggtobak is to be made in a similar way as food) in Sweden (Livsmedelslagen (2006:804)) |

Table A.7 Coverage of novel products under national pharmaceutical regulation

| Product | Coverage of pharmaceutical regulation |
|---|--|
| Electronic cigarettes, e-cigarette or ENDS | Covered fully (has to be approved as a pharmaceutical product) in Sweden (The Medicinal Products Act (SFS 1992:859)). Covered partially in Austria and Denmark (the nicotine part of the cigarette). Uncertain whether covered fully or partially (Nicotine content) in Finland (Pharmaceutical Law 395/1987). Uncertain whether covered in Portugal (Decree-Law 176/2006) |
| Smokeless cigarettes (non-battery operated) | Covered fully in Sweden (The Medicinal Products Act (SFS 1992:859)). Covered partially (Nicotine content) in Finland (Pharmaceutical Law 395/1987) |
| Herbal cigarettes | n.a. |
| Nicotine lollipops | n.a. |
| Nicotine lozenges | n.a. |
| Nicotine toothpick | n.a. |
| Nicotine condoms | n.a. |
| Herbal tobacco or herbal shisha for use in waterpipes | n.a. |
| Nicotine wafers | n.a. |
| Nicotine drink | n.a. |
| Nicotine toothpaste | n.a. |
| Nicotine cream | n.a. |
| Nicotine spray | n.a. |
| Nicotine lip balm | n.a. |
| Tobacco tablets | n.a. |
| Tobacco pellets, sticks and strips | n.a. |
| Tobacco water (tuibur/hidakphu) | n.a. |
| Tobacco-infused drinks | n.a. |
| Red tooth tobacco powder | n.a. |
| Bajjar tooth powder | n.a. |
| Gul (Gadakhu) tooth powder | n.a. |
| Tobacco toothpaste (Quiwam) | n.a. |
| Mishri tooth powder | n.a. |
| Tobacco toothpaste (creamy snuff) | n.a. |
| Tobacco-infused ingredients of cocktails | n.a. |

Table A.8 Coverage of novel products under other national regulation

| Product | Coverage of pharmaceutical regulation |
|---|--|
| Electronic cigarettes, e-cigarette or electronic nicotine delivery systems (ENDS) | Covered fully in the UK (REACH – CHIPS) |
| Smokeless cigarettes (non-battery operated) | n.a. |
| Herbal cigarettes | Covered fully in Sweden (Lag (1994:1563) om tobaksskatt) |
| Nicotine lollipops | n.a. |
| Nicotine lozenges | Covered fully in the UK (REACH – CHIPS) |
| Nicotine toothpick | n.a. |
| Nicotine condoms | n.a. |
| Herbal tobacco or herbal shisha for use in waterpipes | Covered fully in Sweden (Lag (1994:1563) om tobaksskatt) |
| Nicotine wafers | n.a. |
| Nicotine drink | n.a. |
| Nicotine toothpaste | n.a. |
| Nicotine cream | n.a. |
| Nicotine spray | n.a. |
| Nicotine lip balm | n.a. |
| Tobacco tablets | n.a. |
| Tobacco pellets, sticks and strips | n.a. |
| Tobacco water (tuibur/hidakphu) | n.a. |
| Tobacco-infused drinks | n.a. |
| Red tooth tobacco powder | n.a. |
| Bajjar tooth powder | n.a. |
| Gul (Gadakhu) tooth powder | n.a. |
| Tobacco toothpaste (Quiwam) | n.a. |
| Mishri tooth powder | n.a. |
| Tobacco toothpaste (creamy snuff) | n.a. |
| Tobacco-infused ingredients of cocktails | n.a. |