# D3.1 Report on the sources for usage of specific influenza vaccine brands and accessibility

**DRIVE**

**Development of robust and innovative vaccine effectiveness**

**WP3 –Evaluation of studies' quality and feasibility**



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# Document History

| Version | Date | Description |
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| V0.3 | 28 NOV 2017 | Outline |
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| V1.0 | 22 DEC 2017 | Draft full deliverable. |

# Publishable Summary

Key drivers of expected vaccine availability and use in a country, overall and for specific population groups include: the license status in a specific country, vaccine recommendations and programs, coverage and the vaccine procurement and distribution. The objectives of this deliverable are to describe: 1) these aspects and how information on each of the five aspects can support determination of the feasibility of measuring brand-specific influenza VE, specifically the influenza vaccine procurement and distribution systems in selected European countries; 2) Sources of information for each of the five aspects, including accessibility and timing of availability; and 3) Considerations and need for sharing non-publicly available tender and market data between the involved parties. Information was gathered from public health institute and European Union websites and from publications. A survey was conducted to collect information on vaccine procurement and distribution systems in fifteen European countries.

**Vaccine license status** is a pre-requisite for marketing and publicly available in a timely manner, but not indicative of whether a vaccine is marketed in a specific country unless only one or two vaccines are licensed in a country for use, or are in use in a specific age group. **Vaccine recommendations** in EU countries are not brand-specific, but more recently this level of specification has been introduced for children and elderly in a few countries. **Vaccine coverage** data from recent previous seasons is generally predictive of future coverage. Although brand-specific vaccine coverage could be inferred in certain situation, specific data on brand-specific coverage is not available to our knowledge. **Vaccine procurement** takes place through centralized national or regional public tenders, or by clinics or pharmacies that purchase the vaccines from manufacturers and/or wholesalers. Among the surveyed countries, 1-8 brands are available; the number of brands is generally higher where the procurement is not organized via a public tender. In almost half of the countries, only 1 or 2 vaccines are available at the national level (all countries with tenders). Procurement occurs mostly annually. Timing of the procurement outcome varies from 0 to 12 months before the start of the vaccination campaign. Details on public tenders are available in the public domain, though difficult to find and sometimes published late. It is unknown whether pharmacies/clinics would be willing or able to share information on vaccine brands they procured. Manufacturer marketing data is considered sensitive information. **Vaccine distribution data** is only available close to the vaccination campaign and therefore not likely to be sufficiently informative for the upcoming influenza season. **Non-publicly available market data** may be subject to provision of EU competition law. Further explorations on sharing of non-publicly available data are planned.

# List of abbreviations

| | |
|---|---|
| ATC | Anatomical Therapeutic Chemical Classification System |
| CP | Centralized procedure |
| DCP | Decentralized procedure |
| DRIVE | Development of Robust and Innovative Vaccine Effectiveness |
| ECDC | European Centre for Disease Prevention and Control |
| EEA | European Economic Area |
| EMA | European Medicines Agency |
| EU | European Union |
| HCW | Healthcare Worker |
| IFPMA | International Federation of Pharmaceutical Manufacturers & Associations |
| LAIV | Live attenuated influenza vaccine |
| MAH | Marketing Authorization Holder |
| MRP | Mutual recognition procedure |
| MS | Members State |
| OCABR | Official Control Authority Batch Release |
| OMCL | Official Medicines Control Laboratory |
| QIV | Quadrivalent influenza vaccine |
| (a)TIV | (adjuvanted) Trivalent influenza vaccine |
| UK | United Kingdom |
| VE | Vaccine effectiveness |
| VENICE | Vaccine European New Integrated Collaboration Effort |
| WHO | World Health Organization |

# Table of Contents

# 1. Background

The availability of sufficient vaccine coverage by product is a key element to define the feasibility of measuring product-specific influenza vaccine effectiveness (VE) and to allow a targeted approach to the study planning and site selection. Expected vaccine availability and use in a country, overall and for specific population groups, depends on the license status in a specific country, vaccine recommendations and programs, coverage and the vaccine procurement and distribution. Specifically, vaccine procurement is a major determinant of where a certain vaccine brand is expected to be used. However, limited information exists on the influenza vaccine procurement systems in European countries.

# 2. Objectives

The ultimate aim of WP3 Task 3.1 is to inform the feasibility of using a mechanism of site selection prior to the upcoming influenza season, based on specific vaccine brand availability to support achieving brand-specific vaccine effectiveness estimates for a wide range of brands and with adequate sample size. For the implementation of such a mechanism it is necessary to know, in advance of the seasonal vaccination campaign, which vaccine brand(s) are expected to be used, preferably at clinic level, in order to set up prospective studies in selected locations accordingly.

For this deliverable, five aspects of influenza vaccination programs of relevance to determine expected brand use were investigated: 1) license status in a specific country, 2) recommendations and programs, 3) coverage, 4) procurement and 5) vaccine distribution.

The objectives of this deliverable are to describe:

1. These aspects and how the information on each of the five aspects can support determination of the feasibility of measuring brand-specific influenza VE, specifically the influenza vaccine procurement and distribution systems in selected European countries.
2. Sources of information for each of the five aspects, including accessibility and timing of availability
3. Considerations and need for sharing non-publicly available tender and market data between the involved parties.

# 3. Methods

### *Terminology*

The term ‘vaccine procurement’ is used herein to refer to the procedures and/or mechanism(s) at the country, national and/or local provider level by which vaccines are acquired from manufacturers or third parties.
The term ‘clinic’ refers to the site where influenza vaccine is administered as part of the national immunization program (typically GPs but other healthcare providers are included too).

### *Sources of information used for this deliverable*

For this deliverable, we made use of a variety of types of information sources (Table 1). The specific sources are described in the respective sections.

*Table 1. Sources of information for the different topics.*

| | Source of information | | | | |
|---|---|---|---|---|---|
| **Topic** | **Consortium expertise** | **VENICE survey** | **IFPMA survey** | **Publicly available information*** ** | **External expertise** |
| **License status** | X | | | X | |
| **Recommendations and program** | | X* | | X | X** (program) |
| **Volume -coverage** | | X* | | X | |
| **Procurement** | X** | | | | X** |
| **Distribution** | X** | | X* | | X** |

* As published
** Through surveys
*** As referenced in the relevant sections

**VENICE survey**

VENICE is a network, dedicated to Vaccine Preventable Diseases, funded by the ECDC, with the objectives of collecting, sharing and disseminating information on national immunization programmes through a network of professionals and providing information useful to build up methodologies and provide guidance for improving the overall performance of the immunisation systems in the EU/EEA Member States (MS).

National immunization programmes and policies vary among EU/EEA countries; immunisation delivery services, health services infrastructures, systems to monitor vaccination coverage and adverse events are quite different among states, making difficult any comparison of nationally available data. The aim of the VENICE's survey is to collect baseline information on country-specific vaccination recommendations for seasonal influenza for risk groups and other target groups in order to obtain vaccination coverage rates for all EU/EEA MS.

In particular, the European Council Recommendation were encouraged to report on a voluntary basis to the European Commission on the implementation of the recommendation. ECDC-supported VENICE surveys have been identified as being an effective way of doing this. These surveys offer an established mechanism to monitor implementation, with several surveys conducted before and immediately following the Council Recommendation. A total of eight surveys was conducted by VENICE between 2008 and 2015: one pandemic influenza survey and seven seasonal influenza surveys.

**IFPMA survey**

In 2008, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Influenza Vaccine Supply International Task Force (IVS) developed a survey method to assess the global distribution of influenza vaccine doses as a proxy for vaccination coverage rates. To date, the survey has collected data from the vaccine manufacturers cumulatively over the period from 2004 to 2015. The survey is planned to be conducted every 2 years.

**Consortium and external expertise**

Consortium and external experts were interviewed for the survey on vaccine procurement and distribution as described below. Wider consortium expertise was also consulted for the regulatory and legal aspects.

*Structured survey on Procurement and Distribution*

Limited to no information on influenza vaccine procurement and distribution systems in European countries was found in the literature or other public domains. Therefore, a survey was performed to collect the information on these aspects from relevant experts.

**Countries**

Fifteen (15) countries distributed throughout Europe were initially selected for investigation of the influenza vaccine procurement and distribution system. These countries were selected based on:

- Countries for which data collection in DRIVE is expected in the initial season: Finland, Spain, Italy
- Countries who have expressed initial interest to contribute to the data collection in DRIVE in upcoming seasons: Austria, Belgium, Denmark, Estonia, Greece, Netherlands, Slovenia
- Other major countries: France, Germany, Norway, Sweden, United Kingdom (UK).

Additional countries will be added in future updates to this deliverable. At this stage, no information could be collected for Austria, and only very limited information for Estonia.

**Survey**

A structured interview was developed. The interview was piloted (for Greece), after which it was amended into an even more structured format to simplify the interviewing process and increase consistency. The updated survey was piloted (for Italy) and found to be suitable for administration to the remaining countries.

The following topics were covered in the final survey:

1. Organization of the national influenza vaccination program
2. Organization of the procurement of influenza vaccines
3. Timing and stages of the influenza vaccine procurement
4. Variability and diversity of volume and type of influenza vaccine
5. Influenza vaccine distribution
6. Sources of information on procured vaccines

The survey can be found in Annex I.

Surveys were completed for 13 countries. No responses were ultimately obtained for Austria and limited information for Estonia. The survey could be completed through a telephone interview (preferred, n=10) or by writing (n=3). After completion of the survey, a summary was sent to the expert respondent for review and comment.

**Expert respondents**

Relevant experts were identified through the DRIVE consortium members, personal networks of DRIVE consortium members and additional connections provided by the survey respondents. Ten experts were identified who were able to provide information for thirteen countries (Table 2). For Austria none of the approached experts responded to date. Half of the experts were from DRIVE partners. Experts were affiliated with public health institutes (n=7) or vaccine manufacturers (n=5).

*Table 2. Experts that participated in the survey*

| **Country** | **Expert respondent** (DRIVE partner/ external expert) | **Affiliation** | **Role in the organization** |
|---|---|---|---|
| Austria | -* | | |
| Belgium | Paul Kenny (DRIVE partner) | GSK (Wavre, Belgium) | Global Marketing Director Seasonal Flu |
| Denmark | Birgit Neale (external expert) | Statens Serum Institut (Copenhagen, Denmark) | Head of Vaccine Supply Unit |
| Estonia | Irina Filippova (external expert) | Estonian Health Board (Tallinn, Estonia) | Chief Specialist, CD Surveillance and Control Department |
| Finland | Hanna Nohynek (DRIVE partner) | Finnish National Institute for Health and Welfare - THL (Helsinki, Finland) | Team leader Vaccine Programme Development |
| France | Hélène Bricout (DRIVE partner) | Sanofi Pasteur (Lyon, France) | Franchise development, deputy director |
| Germany | Frank Eberlein (DRIVE partner) | Seqirus (Basel, Switzerland) | Head of Commercial Operations |
| Greece | Maura Cambiaggi (DRIVE partner) | Seqirus (Siena, Italy) | Director Commercial Operations Italy |
| Italy | Maura Cambiaggi (DRIVE partner) | Seqirus (Siena, Italy) | Director Commercial Operations Italy |
| Netherlands | Sjirk Kok (external expert) | Dutch National Institute for Health and Environment - RIVM (Bilthoven, The Netherlands) | Senior Advisor Business Operations |
| Norway | Knut Jønsrud (external expert) | Norwegian Institute of Public Health (Oslo, Norway) | Head of Vaccine Supply Unit |
| Slovenia | Staša Javornik (external expert) | Slovenian National Institute of Public Health (Ljubljana, Slovenia) | Head of Vaccine Supply Department |
| Spain | Javier Diez-Domingo (DRIVE partner)<br><br>Toni Lloret (DRIVE partner) | FISABIO (Valencia, Spain)<br><br>Seqirus (Barcelona, Spain) | Director of the Vaccine Research Department<br><br>Director Commercial Operations, Spain |
| Sweden | Hélène Bricout (DRIVE partner) | Sanofi Pasteur (Lyon, France) | Franchise development, deputy director |
| UK | Paul Kenny (DRIVE partner) | GSK (Wavre, Belgium) | Global Marketing Director Seasonal Flu |

*Three potential experts were contacted (Austrian Ministry of Health n=2, Mylan n=1), but no responses were received.

# 4. Results

## 4.1 Vaccine license status

*Introduction*

Medicinal products, including influenza vaccines, must be authorized before they can be placed on the market for use.

The European system offers several routes for the authorization of medicinal products (2):

- **Centralised procedure (CP).** Applications for the centralised procedure are made directly to the European Medicines Agency (EMA) and lead to the granting of a European marketing authorisation by the Commission which is binding in all MS. Compulsory for some products. Applications for multiple Member States for products that do not fall within the mandatory scope of the centralised procedure must follow the mutual recognition procedure (MRP) or the decentralised procedure (DCP).
- **Mutual recognition procedure (MRP).** This procedure is based on the principle of recognition of an already existing national marketing authorisation by one or more MS. The country where the product was first authorized usually acts are the Reference MS. The MAH can select the countries to include in the MRP.
- **Decentralised procedure (DCP)**. Through this procedure an application for the marketing authorisation of a medicinal product (not yet licensed in the EU) is submitted simultaneously in several MS, one of them being chosen as the Reference MS. At the end of the procedure national marketing authorisations are granted in the reference and in the concerned MS. The difference between MRP and DCP is that a product must already be authorised in at least one MS on a national basis in order for MRP to be used. DCP may be used if the product is not already authorised in any MS, but does not want to use the centralised procedure, or the product is not eligible for the centralised procedure. The MAH can select the countries to include in the DCP.
- **National authorisations**. Available for medicinal products to be marketed in one MS only.

Depending on the path for authorisation – information on the authorisation status is available in different sources.

In addition, as per Article 114 of Directive 2001/83/EC it is required that each batch of human vaccines is examined by an Official Medicines Control Laboratories (OMCL) in the EU/EEA prior to placing it on the market. This is referred to as the Official Control Authority Batch Release (OCABR) Procedure.

If the results of the test are satisfactory, the Competent Authority (CA) issues an 'Official Control Authority Batch Release Certificate' to the marketing authorization holder (MAH). OCABR performed by any given MS must be mutually recognized by all other MS requiring OCABR for that product. The MAH must provide a copy of the OCABR Certificate to the CA of the MS where the batch will be marketed. This MS will need to recognize the certificate. Approximately within one week, the batch is then released. Permission is required if that batch is subsequently marketed in a different MS than for which the batch release was originally issued (3).

*Value of the information to determine feasibility of measuring influenza VE and brand availability on a country, regional or local level*

Products which are authorized through the CP or MRP/DCP can theoretically be marketed in all or respectively multiple selected EU MS, but in practice influenza vaccines are not marketed in all possible MS where the vaccine is authorized. The status of the authorization of an influenza vaccine in a MS is thus not indicative on whether a product is also marketed in that MS. In practice, influenza vaccines authorized through the DCP/MRP are commonly marketed in the Reference MS, though this is not required, nor a given.

In contrast, the availability of a certificate for the batch release (or transferred batch release) of an influenza vaccine in a given MS is directly reflective of where the product will be marketed.

The authorization status of influenza products only informs on whether an influenza vaccine can be marketed in a certain country. If a very limited number of vaccines (i.e. one or two) are authorized in a certain country, then this would generally be predictive of which vaccine brands would be marketed.

The availability of a certificate batch release for a given MS indicates with near certainty that a product will be marketed in that MS, except if permission is obtained to transfer the batch release to another MS. This is more the exception than the rule.

*Value of the information to determine volume-coverage on a country, regional or local level:*

The batch release also indicates the number of doses of a batch to be released for a specific MS.

*Source of the information*

An overview of online registers of the MS for nationally-authorized medicine products, that can be used to identify the license status of influenza vaccine in the European MS, can be found here . Table 3 also provides the links to these online registries - with some alternatives - together with a proposed search guidance in local language, where applicable, as well as the link to the obtained search results.

There are some limitations to this online repository:

- The search options do not always allow a targeted search on ‘seasonal influenza vaccine’. Search results based on Anatomical Therapeutic Chemical Classification System (ATC) code or the general term “influenza vaccine” yields a list of pandemic and seasonal influenza products.
- Influenza vaccines have different brand names across MS. The national repositories generally list vaccines by their local brand name. The Product Leaflets listed here can contain information on the brand name applied in the different MS (limited to UK licensed products only) or per the information provided in the Mutual Recognition Information (MRI) Product Index for products licensed through the MRP/DCP procedure. (of note: the presented information appears to be out of date, verification with the respective market authorization holders would be advised).
- The frequency by which the information in these repositories is updated is not always indicated.
- Not all information and interfaces are available in English.

*Table 3. Online resources to identify authorized influenza vaccine in the European Member States*

| Country | Specific online list | Online searchable register | Search guidance* | Search result** | Comments |
|---|---|---|---|---|---|
| Europe | | Community register centrally licensed products | Various search options | | |
| | | European public assessment reports | → select ATC code → search term J07BB | Results J07BB | |
| | | Mutual Recognition Information (MRI) Product Index | | | For products licensed through the MRP/DCP procedure. Provides brand names in Member states**** |
| Denmark | - | Produktresuméer*** | Keyword: Influenzavaccine saesonen | Result Influenzavaccine saesonen | |
| Estonia | - | Ravimiregister | → select ATC code → search term J07BB | - | |
| Finland | - | FimeaWeb | → Select ATC → code Search term: J07BB | | Indicates whether the product is marketed |
| France | Vaccins contre la grippe | - | - | - | |
| Germany | Authorised influenza vaccines | - | - | - | |
| Greece | - | Αναζήτηση προϊόντων | → Select option 3. ATC codes → Search and select J07BB influenza vaccines | | |
| Italy | - | Banca Dati Farmaci dell'AIFA | → Select Cerca Principio Attivo → search term Vaccini influenzali → select Vaccini influenzali | Results vaccine influenzali | |
| Norway | - | Legemiddelsøk | Search J07BB | Results J07BB | Also indicates if the product is marketed |
| Slovenia | - | Centralna baza zdravil | Field ATC oznake search term: J07BB | Results J07BB | |
| Spain | Gripe estacional | Centro de Información online de Medicamentos | → Search term Codigo ATC: J07BB | - | Provides information on type of |

| Country | Specific online list | Online searchable register | Search guidance* | Search result** | Comments |
|---|---|---|---|---|---|
| | | de la AEMPS - CIMA | | | licensure pathway. |
| Sweden | - | Läkemedelsfakta - Utökad sökning | ATC-kod: search term J07BB | - | |
| The Netherlands | - | Geneesmiddelen-informatiebank | →Select 'uitgebreid zoeken' (extended search) → ATC code search term: J07BB | Results J07BB | |
| UK | - | Medicines Information: SPC & PILs | → search term: influenza vaccine | Results influenza vaccine | The package leaflets (PL) for UK authorized products can be found in the electronic Medicines Compendium (eMC). These PLs contains information on brand names in different member states. |

* The completeness of the search results based on these search terms have not been verified.
** Only provided where possible. Results shown as per performed search in Dec 2017.
*** Only opens in Google Chrome/Explorer
**** List of brand names does not appear to be complete or out of date.

### *Accessibility of the information*

Information on the license status in the MS is available in publicly accessible repositories for both centrally authorised products and products authorised via different procedures as listed above. In addition to the license status, some regulatory agencies provide also information on the marketing status of the authorized products (see Finland and Norway in Table 3).

No publicly available information appears to be available on the certification status of the batch release of influenza vaccines.

### *Timing of availability of the information*

Unless a new product is authorized shortly before the influenza season, the authorization status of influenza vaccines in a MS is known in advance of any season.

The certification of the batch release occurs only shortly before the influenza season and distribution of the product. For each marketed batch, the final product is provided to the testing laboratory as soon as the product is available. Requests for testing are addressed on a first come first serve basis. Within one week of the batch release for a market, the product can be marketed.

## 4.2 Influenza vaccine recommendations and vaccination programs

### *Vaccine recommendations*

In Europe, influenza vaccine is generally recommended to older age groups, patients with chronic medical conditions, pregnant women and healthcare workers; in some countries there is also a recommendation for the vaccination of children. Details of the recommendations differ between countries.

### *National influenza vaccination program*

Vaccine recommendations are often used as part of a national immunization program. The following section provides characteristics of the organization of the national immunization program in the selected countries. Data was collected through the structured interview.

*Proportion of doses provided through the national immunization program*

In most surveyed countries, vaccinations provided as part of the national influenza vaccination program accounted for around 95% of the influenza vaccine doses. In Estonia, there is no coordinated national influenza immunization program.

*Vaccine administration*

In most countries, the vast majority of influenza vaccines are administered by GPs (Table 4). In Denmark, in addition to GPs, vaccination clinics play an important role in influenza vaccine administration (ca. 25%). In Sweden, influenza vaccines are administered primarily through vaccination clinics.

In Belgium, France and Greece, patients have to get the vaccine at a pharmacy before going to another healthcare provider for administration.

*Table 4. Healthcare providers that administer influenza vaccine under the national immunization program*

| **Country** | **Vaccine administration (main provider)** | **Vaccine administration (Other)** | **Patient must go to pharmacy prior to administration*** |
|---|---|---|---|
| Belgium | GPs | Pediatricians | Yes |
| Denmark | GPs (70-75%) | Vaccination clinics (25; permanent and temporary); these vaccination clinics go to the people, e.g. libraries, nursing homes<br>Pharmacists (for the past 2 years, this is getting bigger) | |
| Estonia | | Family doctor<br>Health Center<br>Infectious Hospital<br>Travel medicine cabinet | Unknown |
| Finland | Public health nurses in healthcare centers (GP practices) | Some hospital outpatients<br>Some temporary vaccination clinics or pharmacies<br>Commercial: private practices and occupational health | No |
| France | GPs (95%) | Nurses,<br>Pharmacists (pilot in | Yes |

| Country | Vaccine administration (main provider) | Vaccine administration (Other) | Patient must go to pharmacy prior to administration* |
|---|---|---|---|
| | | pharmacy this year, so very few)<br>Hospitals (very few) | |
| Germany | GPs (close to 100%) | Very small % by public health institutes (health centers) | No |
| Greece | GPs | | Yes |
| Italy | GPs (close to 100%) for elderly and at risk | Vaccination clinics<br>Pediatricians | No |
| Netherlands | GPs (97%) | 2-3% long term care facilities | No |
| Norway | GPs | Hospital (employees)<br>Temporary vaccination clinics | No |
| Slovenia | GPs (70%) | Hospital patients and employees (13%)<br>Public health institute (18%) | No |
| Sweden | Permanent vaccination clinics (>95%) | | No |
| UK | Mostly GPs (mostly; incl. vaccination clinics organized by GPs). | Retail<br>Hospital<br>Schools | No |

*Preliminary data. Patient goes to the pharmacy to get the vaccine, and then goes to the GP for administration.

*Start of vaccination*

Across the countries, vaccination starts between the end of September and the end of November (Table 5).

*Table 5. Start of the seasonal influenza vaccination campaigns in different countries*

| Country | Start of vaccination |
|---|---|
| Belgium | October |
| Denmark | October 1st |
| Finland | October/November (current)<br>September/October (as of 2018) |
| France | Beginning of October |
| Germany | Late September/early October |
| Greece | End of October |
| Italy | Mid-October (may differ by region) |
| Netherlands | October |
| Norway | October |
| Slovenia | Mid-October |
| Sweden | End of October/ beginning of November |
| UK | Second half of September |

*Value of the information to determine feasibility of measuring influenza VE and brand availability on a country, regional or local level*

**Vaccine recommendations**

Information on vaccine recommendations is informative on expected influenza vaccine use as it is likely (partially) predictive for the use of influenza vaccine in specific age and risk groups in a country.

Many recommendations do not provide specific recommendations by vaccine type of brand. An exception is for example the UK, where live attenuated influenza vaccine (LAIV (Fluenz Tetra®)) is preferentially recommended for children.

Vaccine recommendations are only informative on vaccine brand availability if specific vaccine types are recommended (as this restricts the number of brands, especially if only one or two vaccines of that type are available) or specific brands are recommended. Also, recommendations for certain age groups are only covered by some brands and may in that case also be informative for use of specific brands.

**Start of campaign**

Information on the timing of the start of the national influenza campaign is informative for the start of the data collection.

*Value of the information to determine volume-coverage on a country, regional or local level:*

By themselves, recommendations do not provide an indication of the vaccine volume, overall or on a brand level. In combination with population demographics on age and comorbidities, the vaccine recommendations can provide an indication of the maximum expected vaccine volume, although vaccine coverage is required to obtain a realistic indication of expected vaccine volume and therefore feasibility of measuring influenza VE.

*Source of the information*

**Vaccine recommendations**

*VENICE survey*

An important source of vaccine recommendations in EU countries is the VENICE survey (4). In their latest publication, vaccine recommendations up to the 2014-2015 season are discussed.

*National websites*

Additionally, national websites provide information on current vaccine recommendations (Table 6). Note that many of these websites are not available in English.

*Table 6. List of websites with national vaccine recommendations for 2017-18*

| Country | Website |
|---|---|
| Belgium | ADVIES VAN DE HOGE GEZONDHEIDSRAAD nr. 9418 Vaccinatie tegen seizoensgebonden griep Winterseizoen 2017-2018 |
| Denmark | Influenza vaccination 2016/2017 |
| Estonia | Vaccination |
| Finland | Vaccination programme for children and adolescents<br>Vaccinations for children and adolescents in at-risk groups<br>Vaccination programme for adults<br>Vaccinating adults in at-risk groups |
| France | Grippe: Généralités |

| Country | Website |
|---|---|
| | Prévenir la grippe saisonnière |
| Germany | Vaccination recommendations by STIKO |
| Greece | Γρίπη και εποχική γρίπη |
| Italy | Stagione influenzale 2017-2018: categorie per le quali la vaccinazione stagionale è raccomandata |
| Netherlands | Voor wie is de griepprik? |
| Norway | Influenza vaccine: Who is the influenza vaccine recommended for? |
| Slovenia | Sezonska gripa in cepljenje - Ogrožene skupine zaradi okužbe z gripo |
| Sweden | Vaccin mot influensa |
| UK | Influenza: the green book, chapter 19 |

*Healthcare professional guidance*

No full overview of guidelines provided to healthcare workers who prescribe or administer influenza vaccine is available. These guidances may be issued at national or at more local level. Overall these guidance documents are not expected to be very different from the information on the public health websites, although in some instances they may contain recommendation on vaccine types.

### *Accessibility of the information*

**Vaccine recommendations**

*VENICE survey*

The results of the VENICE survey are available once published.

*National websites*

National influenza vaccine recommendations are generally publicly accessible and up to date, although they are often only available in the local language.

### *Timing of availability*

**Vaccine recommendations**

*VENICE survey*

The VENICE survey is retrospective and provides recommendations on past influenza seasons, not on the upcoming influenza season. Furthermore, there is a lag time between the time of publication and the season(s) reported on of about 1 to 3 seasons. Given that vaccine recommendations are not rapidly evolving this information is still expected to be indicative of the recommendations for a future season.

*National websites*

Vaccine recommendations are available in advance of the season. Major changes are not very common and are expected to be announced sufficiently in advance of the season to allow implementation.

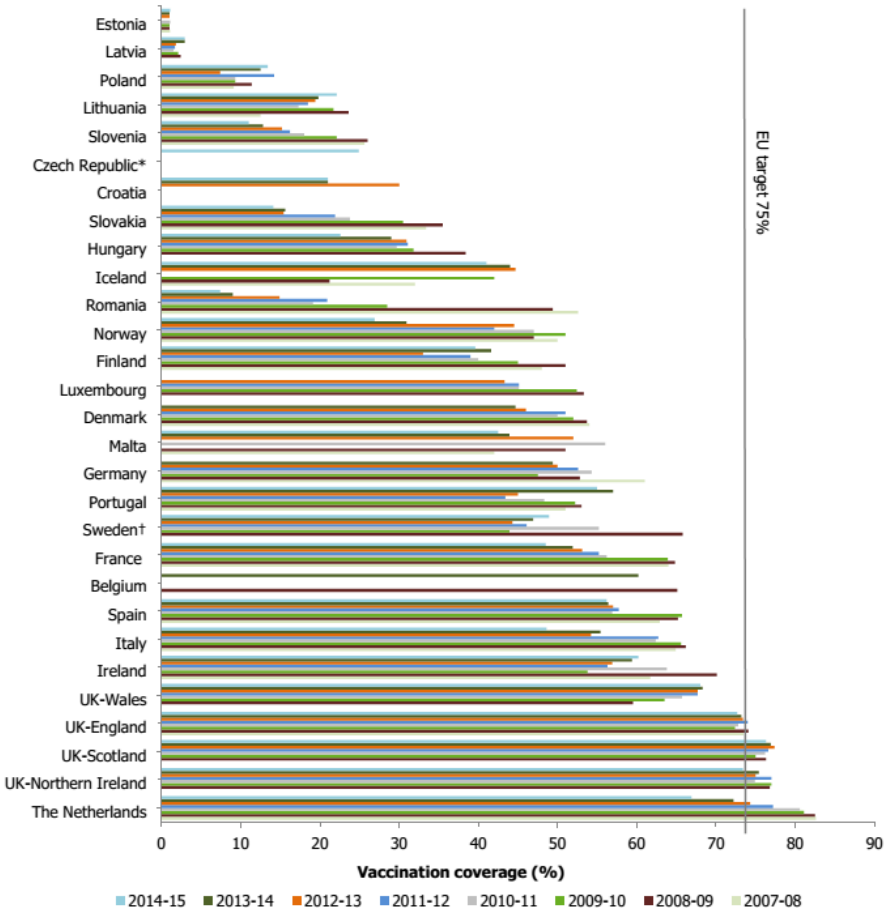
## 4.3 Influenza vaccine coverage

### *Introduction*

In 2009, the European Council issued a recommendation to reach 75% influenza vaccine coverage in older age groups by the 2014-2015 winter season, and to extend this target to include people with chronic conditions (1).

Vaccine coverage data in EU countries as reported by the VENICE survey is shown in Figure 1. In the 2014-2015 influenza season, the EU target was met only in Northern Ireland and Scotland (4). Many countries experienced a decline in vaccine coverage after the 2008-2009 season; and while some have recovered, over half the EU countries had a lower vaccine coverage in 2014-2015 than in 2008-2009 (4).

Methods to estimate vaccine coverage include the use of routine clinical practice data, such as healthcare records or vaccine registry systems, surveys and information on dose distribution.




*Source: National seasonal influenza vaccination surveys, July 2009–December 2015*
** Age groups of over 65 years of age and clinical risk groups combined*
*† Sweden: For the 2009–10 influenza season, reports were received for around 60% of the population.*

*Figure 1. Seasonal influenza vaccination coverage rates in older age groups, 29 EU/EEA Member States, 2007–08 to 2014–15 influenza seasons Source: copied from VENICE survey (4)*

### *Value of the information to determine feasibility of measuring influenza VE and brand availability on a country, regional or local level*

A sufficient vaccine coverage is required to enable reliable implementation of VE studies. Vaccine coverage differs per country and is unknown for some countries. By definition, influenza vaccine coverage for any season is retrospective. Past country-specific vaccine coverage is generally predictive of future vaccine coverage. Most trends in vaccine coverage are gradual, although certain events may cause more drastic changes, such as was observed post 2009-pandemic, in case of safety concerns, or if a new recommendation is implemented. Historical vaccine coverage (overall, by age, in risk groups) can therefore support the assessment of feasibility of estimating VE in a country. If vaccine coverage is historically very low, such as in Estonia or Latvia (Figure 1), obtaining sufficient sample size for brand-specific VE will be very challenging.

Vaccine coverage estimates, overall or by risk group, are generally not vaccine-brand or -type specific. Unless it is known a single vaccine brand would be available in a country during a certain season, vaccine coverage estimates are therefore not informative of brand-specific vaccine availability.
In countries where the tender mechanism specifies a priori how many brands will be chosen and what the possible market shares will be (e.g. 100%, 33,3% vs.66.6%, 40% vs. 60%), information on vaccine coverage can be used to estimate the maximum possible brand-specific volume in a country.

*Value of the information to determine volume-coverage on a country, regional or local level:*
Most sources of vaccine coverage provide national vaccine coverage data, although regional and local level coverage may sometimes be available.

*Source of the information*
Vaccine coverage can often be found in the literature. Two surveys are of special interest, the VENICE survey and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Influenza Vaccine Supply task force survey.

**VENICE survey**
The VENICE survey provides information on vaccine coverage in European Union (EU) and the European Economic Area (EEA), by risk group if available. Most countries calculated vaccine coverage using administrative methods, some used surveys. The results of the VENICE survey are published (4).

**IFPMA survey**
For the influenza IFPMA survey, influenza vaccine manufacturers provide the number of seasonal influenza vaccine doses provided to every WHO MS as a proxy for influenza vaccine coverage. These data for all manufacturers are aggregated at WHO region level and are published (7, 8). The IFPMA survey is conducted every two years.

**National websites**
National websites can provide data on vaccine coverage (Table 7).

*Table 7. National website with data on vaccine coverage – identified to date.*

| Country | Website |
|---|---|
| Finland | Influenza vaccination coverage (map) – 2016-17 (possibility to view by season and age groups of 6m to 35m and 65 years and older)<br>Influenza vaccination coverage 65 years and older (table) – by season and location<br>Influenza vaccination coverage 6m to 35m – by season and location |
| Germany | Influenza coverage rates are published in the "Epidemiologisch Bulletin" of the Robert Koch institute.<br>Latest version: Impfquoten der Rotavirus-, Masern-, HPV- und InfluenzaImpfung in Deutschland |
| Italy | Epicentro Coperture della vaccinazione antinfluenzale in Italia<br>Ministero della Saluto Dati coperture vaccinali |
| Netherlands | RIVM Griepvaccinatiegraad (reports can be found in the column on the right) |
| Spain | Coberturas de Vacunación<br>Most recent data: Evolución coberturas de vacunación antigripal en población ≥ 65 años. |

| Country | Website |
|---|---|
| | España, temporadas 2007-2008 a 2016-2017. |
| UK | Gov.UK Seasonal flu vaccine uptake: figures |

*Accessibility of the information*

Information is publicly available, including the VENICE and IFPMA surveys.
A limitation of the IFPMA survey is that, while aggregate information is publicly available, the raw data specifying the number of doses distributed by each manufacturer is not, thereby limiting the value of the information.

*Timing of availability of the information*

Influenza vaccine coverage for any season is by definition retrospective, but historical data on overall coverage is available in advance of the season for many countries in Europe. There may, however, be a significant lag time between the influenza season for which influenza vaccine coverage is measured and availability of the estimate in the literature, for example because surveys are not conducted annually or the lag time to disclose the results.

## 4.4 Influenza vaccine procurement and distribution

The full report on the vaccine procurement mechanisms and distribution in Europe is available in Annex 2. The original summaries of the country interviews are provided in Annex 3. The sections below present a synthesis of this information and what this implies in relation to determine the expected vaccine brand use based on vaccine procurement and distribution.

Information on 13 countries was collected through surveys. For two countries, no suitable expert has yet been identified.

For Estonia, the information collected was extremely limited: there is no governmental procurement of influenza vaccine, the vaccine is not reimbursed, and the vaccination of influenza vaccine coverage is lowest in the EU (2-3%).

### 4.4.1 Vaccine procurement

*Introduction*

Based on the interviews held with experts from 13 European countries, four main procurement systems were identified:

1. Centralized national public tenders (hereafter referred to as ‘national tenders’)
   (Denmark, Finland, Netherlands, Norway, Slovenia)
2. Centralized regional public tenders (hereafter referred to as ‘regional tenders’)
   (Italy, Sweden, Spain)
3. Purchase of vaccines by clinics, directly from the manufacturer and/or through wholesalers
   (UK)
4. Purchase of vaccines mainly by pharmacies, directly from the manufacturer and/or through wholesalers
   (Belgium, France, Germany, Greece)

The descriptions focus on the average situation in these countries. Deviations may apply in certain situations or across seasons.

*Value of the information to determine feasibility of measuring VE and brand availability on a country, regional or local level*

The informativeness of the vaccine procurement system differs per country. Aspects that influence the informativeness include:

- The use of public tenders (and publicly available information)
- The length of tender contracts (one-year vs. multi-year)
- The number of different vaccine types or brands procured
- The timing of tender award or (pre)bookings (number of months prior to vaccination)
- Where the vaccines are distributed to (clinic vs. pharmacy)

Depending on these factors, in certain situations, it is possible to know prior to the start of vaccination which vaccine(s) will be used at clinic level.

**Tenders**

In countries or regions where tenders are used, information on vaccine brand availability at national or regional level may be indicative of vaccine use at clinic level.

Figure 2 shows the number of brands available, and the proportion of each, at national, regional and clinic level in countries with national tenders. For Finland, Slovenia and Norway, it is possible to know which brand will be used at clinic level as only one brand is purchased for use in adults at national level (Finland[1], Slovenia), or two brands are purchase but only one brand is used in each region (Norway). In Finland and Slovenia, an additional brand is purchased for use in children. In Denmark and the Netherlands, two brands are procured in fixed proportions at national level, and distributed randomly to clinics in a series of deliveries; the brand can change with each delivery.

Figure 3 shows the approximate number of brands available at national, regional and clinic level in countries with regional tenders. For Sweden, it is possible to know which brand will be used at clinic level as only one of two brands is purchased at regional level. For Italy and Spain, vaccine brand availability at regional level is less indicative of use at clinic level as multiple brands are purchased; the number of brands and the proportion of each may vary between regions. Vaccines used at clinic level are subsets of those purchased at regional level and may vary between clinics. In Spain, regions can choose to participate in a national tender (n=9 regions), which is followed by negotiations at regional level, or issue their own regional tender (n=8 regions).

Table 8 shows the number of brands by type procured at national level, if this information was available.

[1] In Finland in 2017, exceptionally two brands of TIV were purchased. This occurred after a new communicable disease act, which expects healthcare workers to be receive influenza vaccine, was implemented and increased an unexpected increase in demand was foreseen.

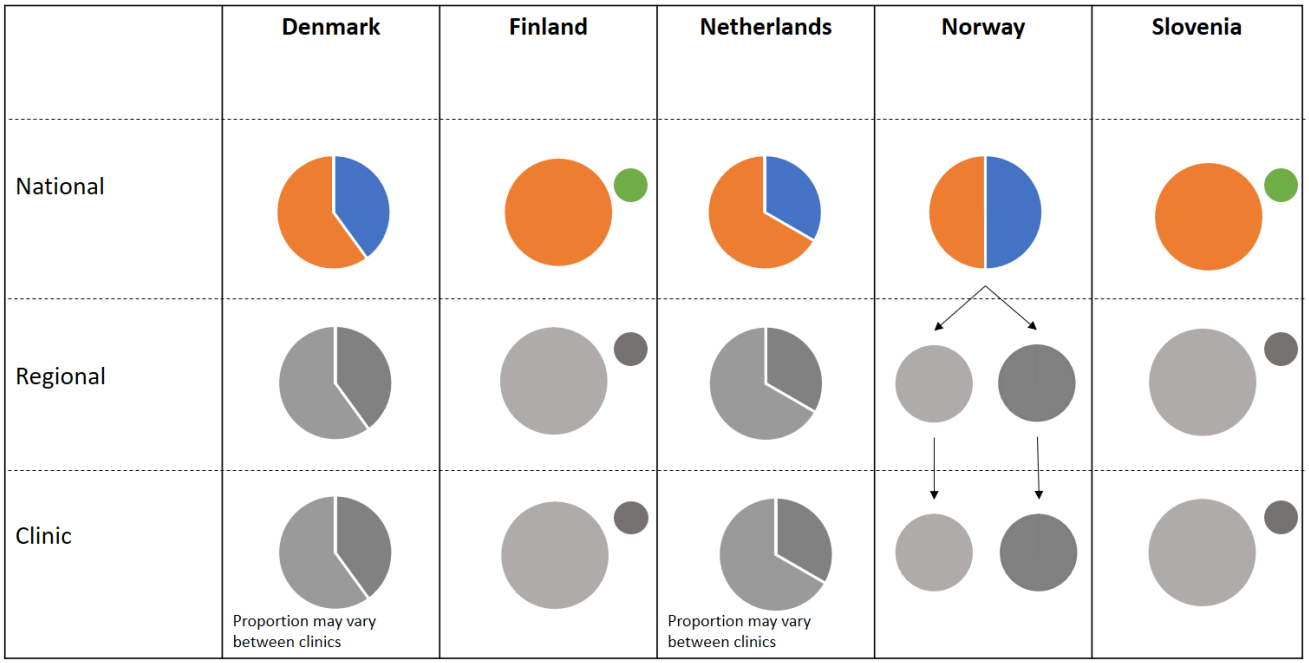



*Figure 2. Brand availability at national, regional and clinic level* ***for countries with national tenders.*** The pie charts show the number of vaccine brands available at each level and the approximate proportion of each, as reported in the survey. For Finland and Slovenia, the large pie charts show vaccines for adults, the small piece charts show vaccine purchased specifically for children. Procurement takes place at the national level (colored), no procurement takes place at regional or clinic level (grey).

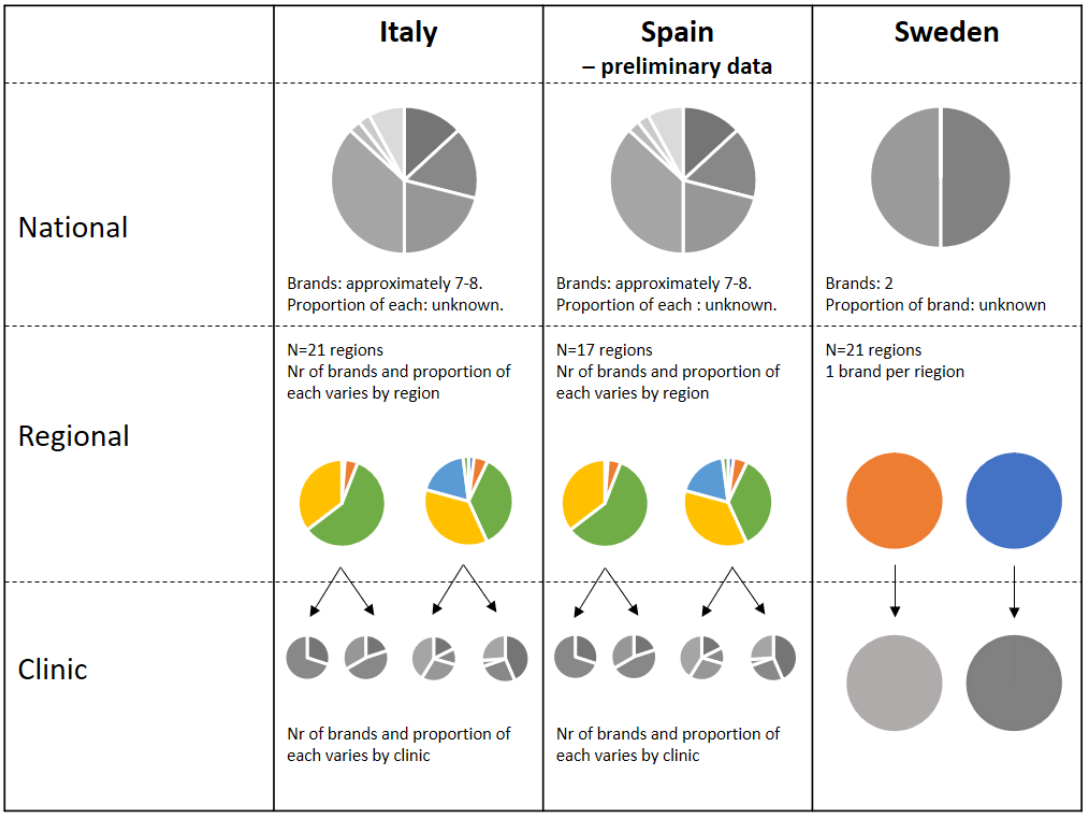



*Figure 3. Brand availability at national, regional and clinic level* ***for countries with regional tenders.*** In Spain and Italy, approximately 7-8 brands are available, the proportion of each at national level is unknown; the number of brands and proportion of each varies by region. For Sweden, 2 brands are available, the proportion of each at national level is unknown; one vaccine is procured by each region. The vaccines available at the

clinic level are (subsets) of those procured at regional level. The pie charts are indicative of the true proportions only for Sweden at regional and clinic level. Procurement takes place at the regional level (colored), no procurement takes place at national or clinic level (grey).

**Direct procurement**

In countries with direct procurement, it is more difficult to state whether vaccine use at national level may be indicative of vaccine use at clinic level. Figure 4 shows the (approximate) number of brands available at national level. The number of brands of brands at clinic level is unknown.

In the UK, GPs order vaccines and therefore decide on vaccine brand availability at clinic level.
In Belgium, France, Germany and Greece, pharmacies procure vaccines. In Germany, the pharmacies distribute the vaccine to GPs. In Belgium, France and Greece pharmacies provide the vaccine to the patient (who then goes to GP for administration). In Belgium and Greece, the GP prescribes the vaccine and can therefore decide the vaccine brand, in France patients receive a voucher from the statutory health insurance.

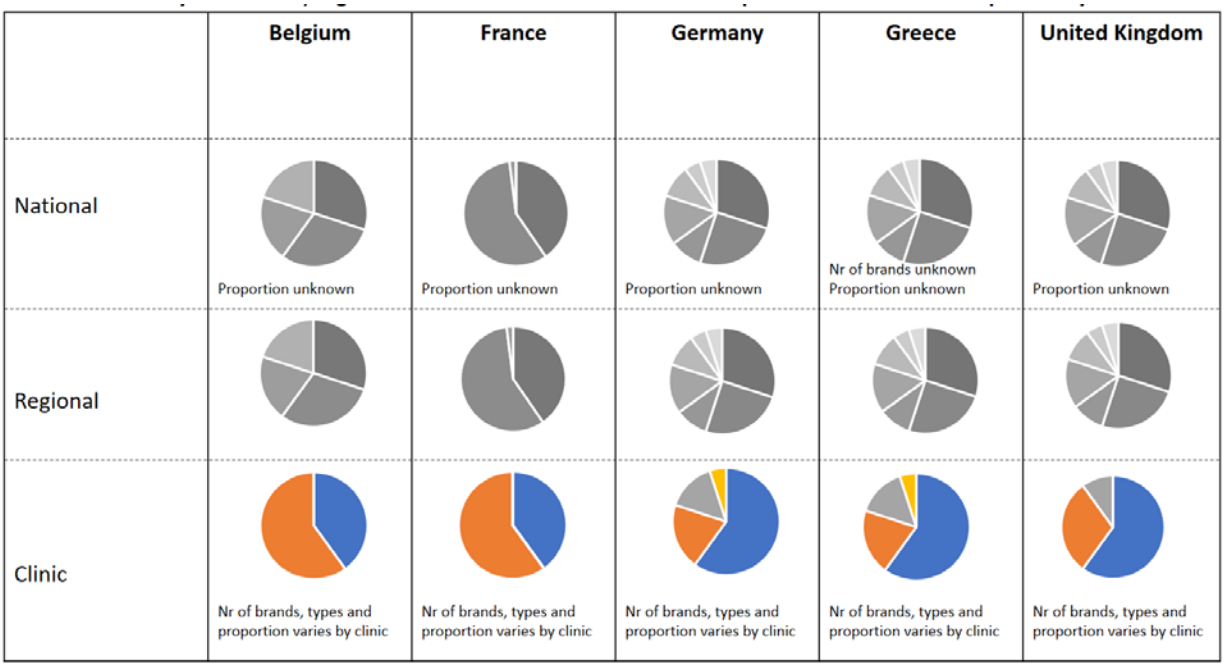



*Figure 4. Brand availability at national, regional and clinic level for countries with* ***procurement at clinic or pharmacy level.*** The pie charts indicate the number of brands available at national level, as reported in the survey; except for Greece. The pie charts are not indicative of the true proportions at any level. Procurement takes place at the clinic (or pharmacy) level (colored), no procurement takes place at national or regional level (grey).

*Table 8. Brand availability at national and regional level, and whether this is indicative of brand use at clinic level*

| | **Nr of brands available at *national* level** | **Nr of brands available at *regional* level*** |
|---|---|---|
| **Belgium** | 2 TIV<br>2 QIV | - |
| **Denmark** | 2 TIV | - |
| **Finland** | 1 TIV<br>1 LAIV | - |
| **France** | 2 TIV<br>1 LAIV | - |
| **Germany** | >4 brands | - |
| **Greece** | >4 brands | - |
| **Italy** | >4 brands | Generally 4:<br>1 TIV<br>1 aTIV<br>1 TIV pediatric<br>1 QIV |
| **Netherlands** | 2 TIV | - |
| **Norway** | 2 TIV<br>1 LAIV | 1 TIV<br>1 LAIV |
| **Slovenia** | 1 TIV<br>1 TIV pediatric | - |
| **Spain – preliminary data** | | Generally but with regional variation:<br>2 TIV<br>2 QIV<br>1 aTIV<br>1 intradermal |
| **Sweden** | 2 TIV | 1 TIV |
| **UK** | >4 brands | |

*For countries with no information in this column, region does not affect vaccine brand availability

*Value of the information to determine volume-coverage on a country, regional or local level:*

**Tenders**

Tenders generally have volume indications per lot, therefore the approximate total volume distributed through the national immunization program at national or regional level is known (although in some cases, such as Norway, the tendered volume is the maximum volume). In some countries, such as Denmark and Italy, the published tender outcome discloses which manufacturer won which lot, thereby providing brand-specific volume data. In the Netherlands, it is not disclosed which manufacturer won which of the two lots. In Norway, the two lots are approximately equal in volume.

**Direct procurement**

In case pharmacies/clinics procure the vaccines, they hold information on brand volume at pharmacy/clinic level. Vaccine manufacturer hold data on brand volume at national level and, in the case of direct sales to pharmacies/clinics, also at pharmacy/clinic level.

Although procurement data likely gives a solid basis for vaccine brand availability, information on expected vaccine volume obtained prior to the season may not reflect actual use, as additional orders may be booked and excess vaccine may be returned to the manufacturers at the end of the season.

*Sources and accessibility of the information*

National and regional tenders are public procurement activities and therefore the information on the tender announcement is generally publicly accessible. Data on vaccine procurement by pharmacies or clinics, and EFPIA or wholesaler sales data is not publicly accessible.

**National tenders**

National tenders are issued by the national public health institute or related institutions (Table 9).

*Table 9. Sources of information for national tenders and their outcome*

| Country | Tender issued/managed by | Website where tender and tender outcome are posted |
|---|---|---|
| **National tenders** | | |
| Denmark | SSI | http://ted.europa.eu |
| Finland | THL | http://ted.europa.eu |
| Netherlands | RIVM | https://www.tenderned.nl/ |
| Norway | FHI | http://ted.europa.eu |
| Slovenia | NIJZ | https://www.enarocanje.si/ |

**Regional tenders**

In Italy, regional tenders are issued by the regional authorities, regional health institutes, or regional tender institutions. In Sweden, the vaccine is purchased through regional tenders (10 regions) and these regional tenders are generally for one lot.

Table 10 shows the websites where tender outcomes have been posted in the past, by region. Note that some regions are missing, as we were not able to identify all relevant regions and websites. Furthermore, it is not yet clear if all influenza vaccine tender outcomes are posted on these websites

*Table 10. Sources of information for regional tenders and their outcome**

| **Country (*Region*)** | Website |
|---|---|
| EU | http://ted.europa.eu (occasionally, regions publish their tenders on this website |
| Italy (9 out of 21 regions) | |
| *Abruzzo* | http://www.regione.abruzzo.it/xGare/ |
| *Campania* | http://www.soresa.it/amministrazionetrasparente/ |
| *Emilia Romagna* | http://intercenter.regione.emilia-romagna.it/servizi-pa/convenzioni |
| *Lazio* | http://www.aslrmf.it/joomla/ |
| *Liguria* | http://www.acquistiliguria.it/ |
| *Puglia* | http://www.empulia.it |
| *Sardegna* | https://www.regione.sardegna.it/ |
| *Veneto* | https://bandi.regione.veneto.it/ |
| *Toscana* | http://www.estar.toscana.it/ns-fornitori/ns-startsda |
| Spain – preliminary data | unknown |
| Sweden | www.opic.com (paid website, part can be accessed through google)<br>https://tendsign.com |

*This list isn't exhaustive not all tenders for every region have been found.

**Pharmacy and Clinic procurement data**

Pharmacies and clinics that buy the vaccines hold data on brand availability and volume at pharmacy/clinic level.

At the moment it is not known whether pharmacies and clinics would be willing to share information on procured vaccine brand and volume. Even if so, data collection may not be feasible due to the very large number of pharmacies and clinics that would have to be contacted.

**Manufacturers**
Manufacturers hold information brand-specific vaccine market information at national level for all countries. In case vaccines are sold to wholesalers, market data is only known at national level. Market data is available at clinic or pharmacy level in case of direct sales. In Belgium, the UK and France, most purchases are direct from the manufacturer (with only some purchase through wholesalers).

One advantage of manufacturer market data compared to pharmacy/clinic procurement data is that the number of companies that would need to be approached to obtain an overview of brand-specific vaccine availability is small compared to the number of pharmacies and clinics that would have to be approached to obtain the equivalent procurement data.

EFPIA market data is considered sensitive information. See section 5.

**Wholesalers**
Wholesalers hold vaccine market data at clinic or pharmacy level. As there is more than one wholesaler per country and wholesalers are not generally strictly geographically organized, regional data is not available. In Greece and Germany, most purchases are through wholesalers (with only some direct purchase from manufacturers). The number of wholesalers can be limited (e.g. 6-7 in Germany) or very large (>50 in Greece).

Wholesaler market data is likely considered sensitive information.

*Timing of availability of the information*

**Tenders**
Tender contracts vary in length, and extensions are possible (Table 11). In Slovenia, tenders are issued annually. In the Netherlands, a tender contract is for one year, with an additional three optional years. In Denmark, Norway and Finland, tender contracts are for two years, with two optional years. In Italy and Sweden, length of tender contracts may vary by region. In Italy, they can vary from one to three years, although one year appears to be most common. In Sweden, tender contracts are typically for four years (unknown how many of these years are optional). In Spain, tender contracts are for one year, although two regions issue two-year tenders.

The timing of tender outcome differs between countries, ranging from well in advance of the vaccination season (November/December of the prior year in the Netherlands) to just before the start of vaccination (e.g. September/October in certain regions in Italy and Spain). There may a significant delay between the actual tender award and signing of the contract with the manufacturer and the publication of the tender outcome on a publicly accessible website.

**Pharmacy and Clinic procurement data**
Procurement information would exist once orders are placed (Table 11), which may be as early as the end of the year prior to the season or as late as September. However, additional bookings (and cancellations) can occur until the contractual deadline.

**Manufacturer's or wholesaler's Market data**
Manufacturer's or wholesaler's market data exists as soon as the (pre)orders are placed.

*Conclusion*
Table 11 shows whether it is possible to know which vaccine brand(s) will be used at the clinic level prior to the start of vaccination.

From Table 11 we concluded that assessing brand-specific vaccine availability using publicly available information is significantly more feasible for countries using tenders than for countries where pharmacies or clinics purchase the vaccines.

*Table 11. Possibility of knowing vaccine brand(s) used at clinic level prior to the start of vaccination*

| | Yes, very likely | Yes, but with limitations | Very difficult or not possible | Timing of information availability |
|---|---|---|---|---|
| **Belgium** | | | Known at pharmacy level (not at clinic level). Multiple brands are used.<br>Not readily available public information. | (Pre)bookings placed in: April-June |
| **Denmark** | | 2 brands are used interchangeably, clinics can receive both in different deliveries* | | Tender outcome: beginning of year<br>Tender contract: 4 years (possibility to cancel). |
| **Finland** | 1 brand for children (procured by THL from manufacturer)<br>1 brand for others (tender) | | | Tender outcome: Q1<br>Tender contract: 2 years + 2 optional years |
| **France** | | | Known at pharmacy level (not at clinic level).<br>In practice only 2 brands are used (pharmacies are free to stock either one or both brands).<br>Not readily available public information. | (Pre)bookings placed in: December of prior year |
| **Germany** | | | Pharmacies distribute vaccine to GPs.<br>Multiple brands are used. | (Pre)bookings placed in: February-May |
| **Greece** | | | Known at pharmacy level (not at clinic level). Multiple brands are used.<br>Most procurement takes place very late (September)<br>Not readily available public information. | (Pre)bookings placed in: pre-bookings as of March, but mostly September |

| | Yes, very likely | Yes, but with limitations | Very difficult or not possible | Timing of information availability |
|---|---|---|---|---|
| **Italy** | | | Tenders organized by region.<br>Late availability of tender outcomes and difficult to identify the outcome of the tender.<br>One vaccine brand per type in each region, but it is unknown at clinic level which type will be used. | Tender outcome: between June and November (depending on the region)<br>Tender contracts: generally 1year, few up to 3 years (depending on the region) |
| **Netherlands** | | 2 brands are used interchangeably, clinics can receive both in different deliveries (in fixed proportion of 33% vs 66%) | | Tender outcome: December.<br>Contract: 1 year + 3 optional years. |
| **Norway** | 1 brand for children (procured by FHI from manufacturer)<br>2 brand for others (tender) (Clinics are told which of the 2 nationally procured brands to order depending on the region they are in.) | | | Tender outcome: varies; orders placed April-May<br>Contract: 2 years + 2 optional years |
| **Slovenia** | 1 brand for children<br>1 brand for others | | | Tender outcome: April<br>Contract: 1 year |
| **Spain** | | | Tenders organized by region, or nationally and renegotiated at regional level.<br>Late availability of tender outcomes and difficult to identify the outcome of the tender.<br>More than one brand per type in some regions, unknown at clinic | Tender outcome: varies June-October<br>Contract: 1 year (except 2 regions: 2 years) |

| | Yes, very likely | Yes, but with limitations | Very difficult or not possible | Timing of information availability |
|---|---|---|---|---|
| | | | level which type will be used. | |
| **Sweden** | Typically, 1 brand per regional tender. | | | Tender outcome: 9-12 months prior to season.<br>Contract: Typically 4 years |
| **UK** | | | Direct purchase by GPs.<br>GP may purchase more than one brand/type.<br>Not readily publicly available information; requires inquiring at GP offices which vaccines were ordered. | (Pre)bookings placed in: Q4 prior to season or Q1 |

*Clinics may order one specific brand if they have a preference. To explore the possibility of asking clinics to order one specific brand.

### 4.4.2 Vaccine distribution

*Introduction*

Distribution data may be of interest to determine brand availability at clinic level. The flow of vaccines flow from the manufacturer to the clinic where the vaccine is administered is illustrated below.

In most countries where tenders are used (Denmark, Italy, the Netherlands, Slovenia, Spain, Sweden), vaccines are stored in warehouses (ran by the public health institute or other) prior to distribution to clinics where they are administered. In Denmark, vaccines can sometimes also be administered by pharmacists.


In Norway and Finland, where a tender is also used, the municipality is responsible for the last step in the distribution chain:


In France, Belgium, and Greece, pharmacies buy the vaccines either directly from the manufacturer or from a wholesaler and provide these to patients, who can then go to a clinic for administration.


In Germany, pharmacies buy the vaccines and distribute these to clinics.


In the UK, vaccines are generally bought by clinics.


This chapter will focus primarily on countries where vaccines are procured by pharmacies or clinics, as the data gaps to determine brand availability are more significant in those countries.

Briefly, in countries where tenders are used, manufacturers generally only hold information on vaccine distribution at national level (or regional, in case of regional tenders) public health authorities can often track vaccines to clinic or pharmacy level. Manufacturer distribution data may be useful in case tender outcomes are difficult to find (this is especially true for regional tenders), incomplete (e.g. in the Netherlands two lots are awarded (1/3 vs 2/3), but it is not made public which manufacturer wins which lot) or when tender results are published a long time after the contract has been awarded.

*Value of the information to determine feasibility of measuring influenza VE and brand availability on a country, regional or local level:*

Influenza vaccine strain composition changes from season to season. Recommendations for the Northern hemisphere vaccine composition are normally issued late February or early March by the

WHO (9). This results in a limited time from between the production of the product and the start of the vaccination campaign.

Shipment data can inform on brand-availability at clinic or pharmacy level, but is generally at the national or regional level. However, unlike sales data, shipment data is unlikely to be valuable in the determination of brand-specific vaccine use at clinic or pharmacy level for our purpose, as this data would only exist immediately prior to the start of the vaccination campaigns, leaving too little time to place prospective studies.

*Value of the information to determine volume-coverage on a country, regional or local level:*

In general, vaccine distribution data is not reflective of actual vaccine use. Excess supply is generally provided, and purchasers have the possibility to return unused vaccines at the end of the season.

*Source and accessibility of the information*

**Manufacturer**

The vaccine manufacturers (or contracted affiliates such as Mylan in the case of Abbott) hold brand-specific vaccine distribution data at national level for all countries. In case vaccines are sold to wholesalers, distribution data is only known at national level. Distribution data is available at clinic or pharmacy level in case of direct sales. In Belgium, the UK and France, most purchases are direct from the manufacturer (with only some purchase through wholesalers).

**Wholesalers**

Wholesalers hold vaccine distribution data at clinic or pharmacy level. As there is more than one wholesaler per country and wholesalers are not generally strictly geographically organized, regional data is not available. In Greece and Germany, most purchases are through wholesalers (with only some direct purchase from manufacturers). The number of wholesalers can be limited (e.g. 6-7 in Germany) or very large (>50 in Greece).

**Clinics or pharmacy level**

Clinics and pharmacy hold information on vaccine distribution once they have received the vaccine deliveries.

**Distributors**

Distributors are often third-party logistics companies. Given that there may be numbers such companies and that they do not have vaccine market data, but only shipment data, obtaining information from them would not only be complex but also not very valuable.

**IFPMA survey**

For the IFPMA survey, total distributed vaccine volume is collected for each manufacturer. This information is not currently collected by vaccine type or at brand level.

*Accessibility of the information*

**Manufacturers**

Distribution data is considered competitive sensitive information (see Section 5).

**Wholesalers and distributors**

It is unknown whether the wholesalers or distributors would be permitted or willing to share the information on the ultimate locations and volumes of brand use for their markets. However, this is

also likely to constitute competitive sensitive information.

**IFPMA**
Due to the sensitive nature of the data, data is processed by a third party and only aggregated vaccine volume data (i.e. not by manufacturer, type, brand) is published. (see section 5)

*Timing of availability of the information*

**Shipment data**
Distribution of vaccines to clinics of pharmacies usually takes place in September, for start of vaccination in October. Multiple deliveries may take place throughout the vaccination campaign.

**IFPMA**
The IFPMA survey is retrospective and published every two seasons. If access to raw data will be granted, this data could be helpful in the historical analysis even if the information is not brand-specific.

# 5. Exchange of non-publicly available vaccine market data by the EFPIA

*The purpose of this section is to serve as a basis for further discussion on the potential competition law implications of the exchange of non-publicly available market data, if so required. It does not represent legal advice. EFPIA and each industry partner will seek independent legal advice in due course of the project on this matter as we progress.*

EU and national competition law applies to the pharmaceutical industry as it does to any other industry. Section 2 of the European Commission's Guidelines on the applicability of Article 101 of TFEU to horizontal co-operation agreements (found at http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52011XC0114(04) provides detailed guidance on the issue. An summary description is provided in Annex 4.

The exchange of genuinely public information is unlikely to constitute an infringement of Article 101. Genuinely public information is information that is generally equally accessible (in terms of costs of access) to all competitors and customers. However, the EFPIA hold information on the brand availability in the MS that may be of value for the implementation of the brand specific vaccine effectiveness studies, but which is not otherwise publicly available. For illustration, Table 12 provides a list of examples of the market data of interest.

Whether such information is competitively sensitive depends on a number of factors, including the structure of the relevant market and the nature of non-public information to be exchanged, i.e.

- the granularity of the information (i.e. by brand, country, region)
- specifications (i.e. size of volume)
- timing (i.e. future vs historical)

To the extent that potentially competitively sensitive information is necessary for the successful

outcome of DRIVE, appropriate safeguards should be introduced.

*Table 12. Examples of market data available within the EFPIA of interest to DRIVE*

| **Examples of market data in order of interest to DRIVE from high to low** |
|---|
| Bidding intentions or submitted tender applications for future season - by brand by MAH |
| Awarded tenders for the upcoming influenza season - by brand or by MAH |
| Certification of batch release for the upcoming influenza season (by definition country, brand, batch and volume specific) |
| Planned or actual distributed country/region volume for upcoming influenza season – by brand, by MAH |
| Historical data on distributed volume of influenza vaccine – by brand or by MAH |
| Historical data on distributed volume of influenza vaccine by country – aggregated across MAHs (as currently presented in the IFPMA survey) |

* Pricing information and contractual terms are not expected to be of interest.

### *Previous experience of the IFPMA Influenza Vaccine Supply (IFPMA IVS)*

Given the importance DRIVE members attribute to compliance, WP3 met with the IFPMA given their previous experience of the IFPMA Influenza Vaccine Supply (IFPMA IVS) task force with the exchange of market data between industry partners in relation to their global survey on vaccine distribution.

As was explained, to ensure compliance with competition regulations in the context of this survey, the industry partners shared only distribution data cumulative across brands for a given country. In addition, the data was collected and aggregated by an independent third-party legal counsel, resulting in an anonymized database of vaccine distribution per country, but no longer by individual industry. In addition, the data concerned an historical period with an approximate one-year lag time between data collection until publication.

In this case, this level of data granularity was sufficient for the intended purpose, namely to assess the global distribution of influenza vaccine doses as a proxy for vaccination coverage rates. While this data is also of interest to DRIVE, in order to support the identification of brand availability and volume on a country level, more granular non-publicly available data would need to be exchanged.

Given the expertise and previous explorations within the IFPMA on this topic, DRIVE-WP3 has placed a request for further discussion of the possibilities in this recognized industry platform. This opportunity is expected to arise around the time of the announcement of the annual strain update of the WHO in February 2018.

# 6. Discussion and conclusion

### *Vaccine license status*

The vaccine license status is a pre-requisite for marketing and publicly available in a timely manner, but not indicative of whether a vaccine is marketed in a specific country unless only one or two vaccines are licensed in a country for use, or are in use in a specific age group. The annual batch release is directly informative of expected brand use in a country, but is not publicly available and the information is only available close to the start of the influenza vaccination campaign.

### *Vaccine recommendations*

In combination with population demographics, recommendations can provide an indication of the maximum expected influenza vaccine volume. Generally, in EU countries vaccine recommendations are not brand-specific, but more recently this level of specification has been introduced for children and elderly in two countries. Vaccine recommendations are available from national public health websites in advance of the season. Data from websites is scattered and often only available in the local language.

### *Vaccine coverage*

Overall influenza vaccine coverage is available for most countries, and for some in age or risk groups. In combination with population demographics, vaccine coverage can give an indication of total influenza vaccine used and an estimate of feasibility to determine vaccine effectiveness on at least at national level and in some instances by risk and age group. Brand-specific vaccine coverage is not generally available. Data on vaccine coverage is publicly available through specific periodic publications, such as the VENICE survey (based on administrative methods or surveys), the IFPMA survey (based on vaccine volume distribution as a proxy for vaccine coverage) and online data reporting by national authorities. Currently, this information is only available for influenza vaccine overall. Vaccine coverage information is retrospective by definition, but data from recent previous seasons is generally expected to be informative of future coverage unless specific events change the public or professional uptake.

### *Vaccine procurement*

Vaccines are procured through centralized national or regional public tenders, or by clinics or pharmacies that purchase the vaccines from manufacturers and/or wholesalers. Among the surveyed countries, brand diversity varies between 1 and 8 different brands per country and is generally higher where the procurement is not organized via a public tender. In almost half of the countries the number of available brands counted at the national is limited to one or two vaccines; these are all countries with national tenders. If more vaccine brands are available in a country, at the clinic level, brand diversity within a season is generally limited to two vaccine brands (per age group if applicable), but will differ between clinics.

Across the surveyed countries, procurement occurs mostly annually. Hence, different vaccine brands may be available from season to season. For public tenders, multi-year contracts are two years with extensions to a maximum of four years in duration. For any new public tenders or bookings, timing of the outcome varies from up to one year before the next campaign to November in the year of the campaign, i.e. only days until the start of the campaign.

Details on public tenders are available in the public domain, though difficult to find. Several limitations to the accessibility of tender information exist. First, there may be a lag time between contract award and publication of the tender outcome; and second, regional tender outcomes are often not easy to find because the information is scattered and only available in the local language. For countries where procurement is not organized through public tenders, none of the information in the procurement process is readily publicly available; it is scattered over all pharmacies/clinics in the country and it is unknown whether pharmacies/clinics would be willing or able to share this information.

### *Vaccine distribution data*

The informativeness of the distribution data from the manufacturers depends on the organization of

the distribution, but generally there is no direct distribution from the manufacturer to the point of care where the vaccine is administered. Hence, distribution data from the manufacturers is only informative for the brand volume available at the country level, and this is only a proxy of the vaccines administered. Local distributors, wholesalers or in some cases pharmacies generally manage the distribution within the countries. Given the number of parties involved in the distribution chain in most countries, separate from whether this would constitute competitive sensitive information, it would be operationally challenging to accumulate the information from all these different parties. Also, the information is only available close to the vaccination campaign.

In summary, knowledge on expected brand use at the national and clinic level is available in countries where tenders are used through which only one or two vaccines are procured even if the information may come late. Specifically, in countries where tenders are organized at a regional level and or procured by GPs or pharmacies, there are gaps in the early knowledge of expected use of specific brands that may be filled with market data from the manufacturers.

# 7. Next steps

- Exploration of possibilities within the boundaries of the competition law to share data among the EFPIA.
- Potentially leveraging data collection and process of sharing data between the EFPIA with the IFPMA Influenza Vaccine Supply Task Force.
- A periodic update is committed for this deliverable.
- Describe vaccine procurement and distribution for the remaining countries
- Deliverable 3.2
  - To collect and analyze historical data on vaccine availability and to determine whether this has a predictive value on future availability of specific brands.
  - To collect data on vaccine availability for the upcoming season to keep the order of the presentation from the text above – accessibility then timeliness.

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# 10. Annex 1 –Survey

*Overall aim: to understand vaccine selection, procurement and distribution system, to know which vaccine brand will be used where, in order to set up prospective brand-specific influenza vaccine effectiveness studies.*

**Topic 1. Organization of the national influenza vaccination program (administration)**

*Aim: to understand if we should focus on national vaccine program or commercial market and to know what type of clinics to go to for prospective studies.*

Background: we would like to understand

1. What proportion of the total country influenza vaccine volume is provided via the national influenza program vs. commercial market?
    a. National influenza vaccination program _____%
    b. Commercial market _____%

2. Which of the following **main** (>20% of total volume) providers administer(s) of the influenza vaccination under the national vaccination program? Roughly, what volume of the national vaccination program is provided by each?
    a. General Practitioners Yes / No _____%
    b. Pharmacist Yes / No _____%
    c. Hospital (inpatients) Yes / No _____%
    d. Hospital (outpatients) Yes / No _____%
    e. Vaccination clinics (permanent) Yes / No _____%
    f. Vaccination clinics (temporarily set up specifically for the influenza vaccination programs) Yes / No _____%
    g. Public health institutes Yes / No _____%

3. Who pays for the vaccines administered under the national vaccination program?
    a. Vaccine recipient
    b. Government
    c. Health insurer
    d. Other, please specify _____

4. Can risk groups choose health care provider for receipt of vaccine? If yes, does their choice have any impact on reimbursement?
    a. No
    b. Yes
        i. Please specify choice they have: _____
        ii. Please specify impact on reimbursement, if any: _____

**5.** Any other comments on the administration of influenza vaccine under the national vaccination program:

---

**Topic 2. Organization of the procurement of influenza vaccines**

*Aim: To understand how and by whom vaccine brands are chosen and at what level this takes place.*

What type of procurement is in place?

a. Public tender
    i. Centrally at national level
    ii. Centrally at regional level, nr of regions _____
b. Preferred provider selection by governmental organization

c. Direct purchase from manufacturers by health care providers
d. Indirect from manufacturer through wholesales or distributors
e. Other, please specify _____

2. What are the main organizations involved in the procurement process of influenza vaccine for the national influenza vaccination program?
   a. Ministry of health
   b. Public health institute
   c. Health insurers
   d. Specific vaccine procurement organizations: _____
   e. Individual healthcare providers: _____
   f. Pooled individual healthcare providers: _____
   g. Wholesalers
   h. Other _____

3. What is the frequency of vaccine procurement?
   a. Annual
   b. Multiyear contracts: _____
   c. Other, please specify _____

4. How many tenders are issued for the country on an annual basis? (e.g. X for X regions)
   _____

5. Who are the main responsible organization(s) involved in the procurement process for the following activities:

   a. Forecasting of required volume: responsible party: _____
   b. Issuing and managing of the public tenders, responsible party: _____
   c. Decision making on the selection of vaccines at national level, responsible party: _____
   d. Decision making on the selection of vaccines at regional level, responsible party: _____
   e. Decision making on the selection of vaccines at clinical level, responsible party: _____
   f. Other, please specify _____

6. Discuss other specifics of procurement system:

7. If there is any significant (>20%) influenza vaccine procurement outside the national influenza vaccine program, how is this organized and for whom (e.g. private health care, nursing home, school programs, hospital etc.)

8. Are there separate procurement systems for different risk populations? (e.g. in categories for age groups)
   a. No
   b. Yes, please specify:

9. Any other comments on the organization or procurement of influenza vaccine under the national vaccination program:

**Topic 3 Timing and stages of the influenza vaccine procurement**

*Aim: To understand when it is known what vaccine brands will be used (from national down to clinic level)*

1. When (what month) are influenza vaccine volume forecast done (if applicable)?

2. Please describe the timing of the main steps in the influenza vaccine procurement process and timing therefore.

    a. Trigger that starts procurement process: _____
    Timing: _____
    b. First awarded tender/pre-bookings: _____
    Timing: _____
    c. Final awarded tender/final booking: _____
    Timing: _____

3. When do health care providers who administer and/or pharmacies who fill the prescription become aware which vaccine brand(s) will be available for use at their clinic (or pharmacy).

---

4. When are vaccines distributed to the clinical sites or pharmacies (especially in relation to start of vaccination)?

---

5. What is the start of the seasonal vaccination? (including regional variation)

    _____

6. Any comments on the timing and stages of influenza vaccine procurement under the national vaccination program:

    _____

**Topic 4. Variability and diversity of volume and type of influenza vaccine**

*Aim: To understand if historical vaccine data can help to predict which vaccine brands will be used in future years*

1. Is there notable and consistent historical variability in the total volume that is tendered? If so, why?
    a. No
    b. Yes, please specify reason: _____

2. Is there notable and consistent historical variability in the brand availability? If so, why?
    a. No
    b. Yes, please specify reason: _____

3. How many **manufacturers** supplying influenza vaccine to the country are considered each year?
    - Average: _____
    - Pre-specified minimum: _____ / Not applicable
    - Pre-specified maximum: _____ / Not applicable
    - Current:

4. How many influenza vaccine **brands** are available each year at a national level?
    - Average: _____
    - Pre-specified minimum: _____ / Not applicable
    - Pre-specified maximum: _____ / Not applicable

- Current:

5. How many influenza vaccine **types** are available each year at a national level?
    a. Average: _____
    b. Pre-specified minimum: _____ / Not applicable
    c. Pre-specified maximum: _____ / Not applicable
    d. Current:

6. Does the availability of different vaccine brands and types differ at a regional level differ from the availability of vaccines at the national level? i.e. can specific vaccine availability (vaccine brand, vaccine type) be derived from vaccines procured at regional or national level?

7. Are there separate procurement categories by **type** of vaccine?

    a. No
    b. Yes, for the following types:
        i. Conventional
        ii. QIV
        iii. Adjuvanted
        iv. Cell-based
        v. Nasal
        vi. Other_____

8. If yes, please describe procurement mechanism

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9. How many different vaccine **brands** are generally procured per vaccine **type**?
    a. Conventional: _____
    b. QIV: _____
    c. Adjuvanted: _____
    d. Cell-based: _____
    e. Nasal: _____
    f. Other: _____

10. Any comments on the variability and diversity of volume and type of influenza vaccine under the national vaccination program:
    _____

**Topic 5. Influenza vaccine distribution**

*Aim: To understand if distribution data can be used to know which vaccine brand is used where*

1. What are the steps in the distribution process manufacturer to the clinical location where the vaccine will generally be administered, and what organization is responsible for each step (including intermediate logistical parties)?
    a. Step 1: _____
    Organization: _____
    b. Step 2: _____
    Organization: _____
    c. Step 3: _____
    Organization: _____
    d. Step 4: _____
    Organization: _____

2. What party/parties involved in the above distribution chain hold information on which vaccines are available at the clinical site?

3. Is the vaccine distribution organized by region?
    a. Yes, specify nr of regions….
    b. No

11. What is the average number of different distributors which ultimately supply the vaccine to the relevant clinical location where the vaccine will be administered for the country?
    a. Exact number: _____
    b. <10
    c. 10-50
    d. 50-250
    e. >250

**Topic 6. Sources of information on procured vaccine(s)**

*Aim: To known who holds data on the vaccines brands used at different levels and if it this data is publicly accessible*

1. Who holds which data on the procured vaccines (brand, volume, batch, date of delivery, date of administration) at each level (national, regional, clinic), and how is this data obtained?

| | **Level: National** | **Level: Regional** | **Level: Clinic** | **How is data obtained?** | **Where is information held within organization?** | **Format in which information is held** |
|---|---|---|---|---|---|---|
| **Manufacturer** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |
| **Vaccine tender organizations (if applicable)** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |
| **Ministry of health** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |
| **National public health institutes** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |
| **Wholesalers** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |
| **Pharmacies** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Batch | | | | | | |
| **Other:** | | | | | | |
| Brand | | | | | | |
| Volume | | | | | | |
| Batch | | | | | | |

2. Is the outcome of the vaccine procurement made public?
    a. No (skip to question 4)
    b. Yes

3. If yes, what information is publicly available, where and when?

| | Publicly Available Yes/No | **Where** can the information be found | **When** is information available |
|---|---|---|---|
| List of manufacturers | | | |
| List of vaccine types | | | |
| List of vaccine brands | | | |
| Volume | | | |
| Total | | | |
| By manufacturer | | | |
| By vaccine type | | | |
| By vaccine brand | | | |
| Other | | | |
| End destination | | | |
| Level of detail: _____ | | | |
| Other | | | |

4. If any of the above data is not publicly available, would it still be possible to request access?

**Topic 7. Other**

1. Any information source that describes further details of the vaccine procurement, or ways in which use of brand-specific influenza vaccine can be known at clinic level prior to season start

# 11. Annex 2 – Report on the vaccine procurement mechanisms and distribution

We looked for information for fifteen European countries. For two countries, Austria and Spain, we have not yet been able to establish contact with an expert. For Estonia, the country with the lowest vaccine coverage in Europe (2-3%), we learned there is no centralized procurement system, but were not able to find out details on how the procurement system does work. In the sections below, we describe the findings from the interviews for Belgium, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Norway, Slovenia, Sweden and the UK.

## Influenza vaccine procurement

*Terminology*

The term 'vaccine procurement' is used herein to refer to the procedures and/or mechanism(s) at the country, national and/or local provider level by which vaccines are acquired from manufacturers or third parties.

The term 'clinic' refers to the site where influenza vaccine is administered as part of the national immunization program (typically GPs but other healthcare providers are included too).

*Type of procurement*

Four main procurement systems are discerned: national tenders (n=5), regional tenders (n=3), purchase by clinics, directly from manufacturers or through wholesalers (n=1), and purchase by pharmacies, directly from manufacturers or through wholesalers (n=4) (Table 13). In Belgium, UK and France, most purchase is directly from the manufacturer, with only some purchase through wholesalers; whereas in Greece and Germany most purchase is from wholesalers, with some direct purchase from manufacturer. In certain areas of the UK, such as Scotland, public tenders are used. In Spain, regions may issue a regional tender (n=8/17 regions), or participate in a national tender (n=9/17 regions) after which they renegotiate the vaccine price at regional level.

*Table 13. Main procurement system for the national influenza vaccination program*

| | **Tender** | | **Purchase directly from manufacturers and/or through wholesalers by** | | **Main player** |
|---|---|---|---|---|---|
| | **National** | **Regional** | **Clinics** | **Pharmacies** | |
| **Belgium** | | | | X | Pharmacies |
| **Denmark** | X | | | | SSI |
| **Estonia*** | | | | | Unclear |
| **Finland** | X | | | | THL |
| **France** | | | | X | Pharmacies |
| **Germany** | | | | X | Pharmacies |
| **Greece** | | | | X | Pharmacies |
| **Italy** | | X (n=20) | | | Differs by region, e.g. regional government |
| **Netherlands** | X | | | | RIVM |
| **Norway** | X | | | | FHI |
| **Slovenia** | X | | | | NIJZ |

| | Tender | | Purchase directly from manufacturers and/or through wholesalers by | | Main player |
|---|---|---|---|---|---|
| | **National** | **Regional** | **Clinics** | **Pharmacies** | |
| **Spain – preliminary data** | (X) | X** | | | Ministry of Health<br>Regional governments |
| **Sweden** | | X (n=10) | | | Regional tender organizations |
| **UK** | | (X) | X | | GPs |

*There is not centrally organized procurement system in Estonia. Unclear how procurement takes place and who the main parties are.
**8/17 regions issue a regional tender, 9/17 regions participate in a national tender and renegotiate at regional level

*Timing and accessibility of procurement outcome*

Details on the tender outcome, including timing, available information and the website the results can be accessed and length of the contract (including possible extensions), are presented in Table 14. In addition, the information on the timing of the last and next expected tender are listed.

*Table 14. TENDERS: Details on availability of tender results, timing and length of contract.*

| | **Timing of tender outcome** | **Tender results in public domain (incl. name of manufacturer)** | **Tender results include manufacturer (M) and volume by manufacturer (V)** | **Length of tender contract** | **Last tender award (first influenza season covered by tender)** | **Next tender award expected (first influenza season covered by tender influenza season)** |
|---|---|---|---|---|---|---|
| **National tenders** | | | | | | |
| *Denmark* | Beginning of the year | http://ted.europa.eu | M: Yes<br>V: Yes | 2 years + 2 optional years (10) | August 2016 and published October 2016 (2016-17) (10) | End of 2018/start 2019 (2019-20) |
| *Finland* | Q1 (published in August) | http://ted.europa.eu | M: Yes<br>V: No | 2 years + 2 optional years (optional years used: varies) | Early 2016 (2016-17) | |
| *Netherlands* | December of prior year | www.tenderned.nl | M: Yes<br>V: No (33% vs. 66%) | 1 year + 3 optional years (optional years used: usually yes) | November 2015 and published December 2015 (2016-17) (11) | |
| *Norway* | Varies, but bookings out by April-May | http://ted.europa.eu | M: Yes<br>V: Yes (maximum V) | 2 years + 2 optional years | | For 2019-20 influenza season |

| | Timing of tender outcome | Tender results in public domain (incl. name of manufacturer) | Tender results include manufacturer (M) and volume by manufacturer (V) | Length of tender contract | Last tender award (first influenza season covered by tender) | Next tender award expected (first influenza season covered by tender influenza season) |
|---|---|---|---|---|---|---|
| *Slovenia* | April (website updated every 3 months) | https://www.enarocanje.si/ | M: Yes<br>V: No (but available upon request) | 1 year | | |
| **Regional tenders** | | | | | | |
| *Italy* (regional details in Appendix 2) | June-November (depending on region) | *Abruzzo*<br>http://www.regione.abruzzo.it/xGare/<br>*Campania*<br>http://www.soresa.it/amministrazionetrasparente/<br>*Emilia Romagna*<br>http://intercenter.regione.emilia-romagna.it/servizi-pa/convenzioni<br>*Lazio*<br>http://www.aslrmf.it/joomla/<br>*Liguria*<br>http://www.acquistiliguria.it/<br>*Puglia*<br>http://www.empulia.it<br>*Sardegna*<br>https://www.regione.sardegna.it/<br>*Veneto*<br>https://bandi.regione.veneto.it/ | M: Yes<br>V: Yes | 1-3 years (depending on the region) | Varies by region | Varies by region |

| | Timing of tender outcome | Tender results in public domain (incl. name of manufacturer) | Tender results include manufacturer (M) and volume by manufacturer (V) | Length of tender contract | Last tender award (first influenza season covered by tender) | Next tender award expected (first influenza season covered by tender influenza season) |
|---|---|---|---|---|---|---|
| | | *Toscana*<br>http://www.estar.toscana.it/ns-fornitori/ns-startsda<br>http://ted.europa.eu<br><br>NB: not all regional tenders have been identified | | | | |
| *Spain – preliminary data* | 0-4 months prior to season | unclear | Unclear | 1 year (except 2 regions where the length is 2 years) | Unclear | Unclear |
| *Sweden* (regional details in Appendix 3) | 9-12 months prior to season | http://ted.europa.eu<br>www.opic.com (paid website, part can be accessed through google)<br>https://tendsign.com<br><br>NB: not all regional tenders have been identified | M: Yes<br>V: unknown | Typically 4 years | Varies by region | Varies by region |

Similarly, Table 15 provides details on orders placed.

*Table 15. DIRECT PURCHASE: timing and availability of information*

| Country | Orders placed | Information on brand held by | Orders in public domain |
|---|---|---|---|
| **Belgium** | Q2 prior to the season | Pharmacies | No |
| **France** | December prior year | Pharmacies | No |
| **Germany** | February to May prior to the season | Pharmacies | No |
| **Greece** | Pre-orders March, otherwise procurement starts in September | Pharmacies | No |
| **UK** | Q4 or Q1 prior to the season | GPs | No |

## Volume and number of brands

*Volume*
Experts reported that the volume of influenza vaccines has been relatively stable over the past years in Belgium, Denmark, France, and Sweden. In the UK, a change in recommendations led to an increase in the volume distributed to children. Experts from Germany, Italy, the Netherlands and Spain reported decreasing volumes over the past year, although the negative trend has stopped for Italy last season. An increase in volume was reported for Finland and Norway this year. In Slovenia, the volume varies, last year there was a decrease but this year there was an increase in the volume.

*Number of vaccine brands*
The current number of vaccines brands that are used at national, regional and clinic level is described in Table 16.

One brand at national level
In Finland and Slovenia, only one vaccine brand is procured for the non-pediatric population.

Two brands at national level
In Denmark, the Netherlands, two brands of TIV are nationally procured (the volume distribution by brand is 40% vs 60% in Denmark, one third vs. two thirds in the Netherlands). The two vaccines are considered to be interchangeable. Vaccinators receive multiple influenza vaccine deliveries throughout the season and the vaccine brand can change with each delivery. In France, two TIV brands are available for the non-pediatric population.

One brand at regional level
In Sweden, two TIV brands are considered overall, but only 1 of the two is procured by each region.
In Norway, two TIV brands are nationally procured however each region receives only one of the two brands.

Multiple brands
In Belgium, Germany, Spain and the UK, a mix of vaccine types and vaccine brands is available. In Italy, four vaccine types are procured by each region (TIV, QIV, aTIV, intra-dermal TIV), each region

procures one brand per type. In Spain regions generally procure multiple vaccine types and brands, although some regions may restrict procurement to one brand per type.

Some countries where QIV isn't used yet have reported this will likely change in the near future.

*Table 16. Current number of vaccine brands used by type (if applicable)*

| Country | National | Regional | Clinic |
|---|---|---|---|
| Belgium | 2 TIV<br>2 QIV<br>(unknown: adjuvanted, cell-based, nasal) | Not applicable | Unknown |
| Denmark | 2 TIV | Not applicable | 1 or 2 (unknown beforehand) |
| Finland | 1 TIV<br>1 LAIV (pediatric) | Not applicable | 1 TIV<br>1 LAIV (pediatric) |
| France | 2 TIV<br>1 LAIV (little used) | Not applicable | Unknown |
| Germany | 7 | Not applicable | Unknown |
| Greece | Unknown | Not applicable | Unknown |
| Italy | TIV<br>QIV<br>aTIV<br>intra-dermal TIV<br>(unknown: number of brands per type) | Generally 4 (3+1 for children?) | Unknown |
| Netherlands | 2 TIV | Not applicable | 1 or 2 (unknown beforehand) |
| Norway | 2 TIV<br>1 nasal | 1 TIV | 1 |
| Slovenia | 2 TIV (pediatric +other) | Not applicable | 1 per age group |
| Spain – preliminary data | | Generally, but with regional variation:<br>2 TIV<br>2 QIV<br>1 aTIV<br>1 intradermal | Unclear |
| Sweden | 2 TIV | 1 | 1 |
| UK | 5 TIV<br>2 QIV<br>1 intra-nasal | Not applicable | Generally at least one per age group + QIV LAIV |

LAIV: live-attenuated influenza vaccine: QIV: quadrivalent influenza vaccine; TIV: trivalent influenza vaccine;

## Distribution information

**Tenders**

In most countries where tenders are used (Denmark, Italy, the Netherlands, Slovenia, Spain, Sweden), vaccines are stored in warehouses (ran by the public health institute or other) prior to

distribution to clinics where they are administered. In Demark, vaccines can sometimes also be administered by pharmacists.


In Norway and Finland, where a tender is also used, the municipality is responsible for the last step in the distribution chain:


In countries where tenders are used, manufacturers hold brand-specific distribution data at national level (or regional level in case of regional tenders), but not at pharmacy or clinic level. The public health authorities usually do hold information on vaccine distribution at pharmacy or clinic level. In the Norway, the public health institute knows what clinics ordered but only have distribution data up to municipality level).

**Purchase by pharmacies or clinics**

In France, Belgium, and Greece, pharmacies buy the vaccines either directly from the manufacturer or from a wholesaler and provide these to patients, who can then go to a clinic for administration.


In Germany, pharmacies buy the vaccines and distribute these to clinics.


In the UK, vaccines are generally bought by clinics.


Manufacturers hold brand-specific vaccine distribution information at national level for all countries, but only at pharmacy or clinic level in case of direct sales. In case a wholesaler is used, the wholesaler, rather than the manufacturer, holds data on distribution information at pharmacy or clinic level. In many countries, a combination of direct sales and wholesalers is used.

In case contract affiliates market, the vaccine, such as Mylan in the case of Abbott, the contract affiliate will hold distribution data rather than the manufacturer.

Regulatory or governmental agencies were identified as a potential source of information for obtaining data on vaccine distribution. For example, in Greece, vaccines are electronically tracked in real-time by the authorities throughout the distribution process. This source of information has not yet been explored.

**Timing and accessibility**

*Sales data*

Manufacturer's sales data and wholesaler's sales data would be valuable in order to determine brand-availability at clinic or pharmacy level. This information would exist once orders are placed (Table 11), which may be as early as the end of the year prior to the season. The advantage of using sales data rather than clinic or pharmacy procurement data is that a limited number of companies (manufacturers and wholesalers) would have to be approached, compared to hundreds of pharmacies and clinics. However, sales data is not readily available. See section 5.

*Shipment data*

Distribution of vaccines to clinics of pharmacies usually takes place in September, for start of vaccination in October. Multiple deliveries may take place throughout the vaccination campaign. It is not yet clear how feasible it would be to access shipment information. Unlike sales data, however, actual distribution data is unlikely to be valuable in the determination of brand-specific vaccine use at clinic or pharmacy level, as this data would only exist immediately prior to the start of the vaccination campaigns, leaving too little time to place prospective studies.

# 12. Annex 3 – Original interview summaries

## Belgium

Monday December 4th, 2017. 11.00-11.25.
*Belgium: Paul Kenny (GSK), additional input from email Germaine Hanquet (KCE, Belgian Health Care Knowledge Centre)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Belgium, the vast majority of vaccines are administered under the national influenza program, although there is no organized vaccination "programme" as such, only recommendations. GPs prescribe the vaccine he/she thinks will be most suited for his/her patient, the patient goes to get the vaccine at the pharmacy, and the GP administered the vaccine. The GP may prescribe either only a vaccine type or a brand, but there is potential for brand-switching by the pharmacist. The national health insurer reimburses the vaccine partly for the risk groups defined by the health council (Hoge Gezondheidsraad).

**Topic 2 – Organization of the procurement of influenza vaccines**
Pharmacies purchases vaccine annually; they do so in collaboration with GPs who may express preference for type or brand. Most pharmacies purchase directly from the manufacturers, some purchase from wholesalers.
The exception is a partial tender in Vlaanderen for institutions (nursing homes mainly), because the Flemish agency distributes it. There is nothing similar on the Wallonia side.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Prebookings are placed in Q2 (April-May-June), for distribution in September and start of vaccination in October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The total volume has remained moderately stable over the years. However, the QIV/TIV ratio is changing; in Belgium the majority of vaccines are already QIV.
Currently 3 main manfucturers sell vaccine in Belgium. Currently the main vaccines available are two TIVs and two QIVs.

Pharmacies buy multiple vaccine types and may buy more than one brand per type (incl. for different age groups) if they wish.

**Topic 5 - Influenza vaccine distribution**
Manufacturers or wholesalers distribute the vaccines to pharmacies.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds brand, volume and batch information up to pharmacy level (in case of direct purchase) or up to wholesaler level. The wholesalers have information up to pharmacy level.
The outcome of vaccine procurement is not made public.

**Conclusion**
In Belgium, most vaccines under the national influenza vaccination program are prescribed by GPs, gotten at pharmacies, and administered by GPs. Pharmacies purchase vaccines, in consultation with GPs, directly from manufacturers or through wholesalers. Pre-bookings are placed in Q2.

## Denmark

Tuesday November 21st, 2017. 8.30-9.10
*Denmark: Birgit Neale (Statens Serum Institut (SSI))*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Denmark, approximately 95% of the influenza vaccines are provided under the national influenza vaccine program. The majority of vaccines are administered by GPs, approximately 25% are administered by vaccination clinics (both permanent and temporary clinics that go to libraries, nursing homes etc.), and a small percentage is administered by pharmacists. The latter started two years ago, and the percentage is increasing. The influenza vaccination program including vaccine administration is funded by government. The clinics pay when they buy vaccine either from SSI (majority) or pharmacies (minority, but cheaper as they sell left over vaccine) and are later reimbursed. Risk group patients can choose their vaccine provider, at no impact on reimbursement.

**Topic 2 – Organization of the procurement of influenza vaccines**
A tender is used at national level for conventional trivalent vaccine. The tender is for a 4 years contract, with the possibility of cancelling if prices fluctuate or if new vaccines become available. Two different manufacturers are chosen, one obtains 40% of the market share, the other 60%.
SSI forecasts the required volume, issues and manages the public tender and takes a decision on the selection of vaccines at national level. The SSI receives advice from the Danish board of health. If clinics have a preference for one of the two vaccines, they can indicate this, otherwise the brand they receive depends on the delivery.
The next tender will be for the season 2019-2020. The situation may change as quadrivalent vaccine will be considered.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Tenders are published on the EU tender website http://ted.europa.eu/TED/. The next tender is expected to be published towards the end of 2018, and awarded either at the end of 2018 or at the beginning of 2019. Orders to the manufacturers will take place in March.
Clinics become aware of the brand that will be used once they receive the vaccine delivery (unless they have expressed preference for a specific vaccine). The first delivery takes place in the week before October 1st. Vaccination starts on October 1st. After this, clinics can order additional influenza vaccine on a weekly basis. The vaccine brand can be different every delivery.
90% of Danish vaccine delivery takes place between the last week of September and the first two weeks of October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The volume ordered every year is relatively stable (730-780,000 vaccines per year). The brands are the same for 4-year periods. The last tenders were for two brands of conventional trivalent vaccine. In the next tender, this may change as quadrivalent vaccine will be considered.
In the past, nasal vaccine for children and cell-based vaccine have been available. These were bought by SSI as single purchase from the manufacturer, without tender process. These vaccines are currently not available.

**Topic 5 - Influenza vaccine distribution**
At the beginning of September, vaccines are delivered to the SSI warehouse in Copenhagen and clinics can order vaccines from SSI. Deliveries start the last week of September and are performed by a contracted cold chain company. After this, each clinic receives up to 1 free delivery a week. Most deliveries take place in the last week of September and the first two weeks of October.

**Topic 6 - Sources of information on procured vaccines**
Manufacturers only know what they have sold to SSI, they do not have the details on distribution to

clinical sites.
SSI has a tracking system (to allow for vaccine recall) that holds all details on each vaccine down to clinic and patient level.
The outcome of the vaccine tender is made public on http://ted.europa.eu/TED/ soon after the tender has been awarded. This includes the name of the two chosen manufacturers but not the vaccine brand (although this can easily be deduced as both are for conventional trivalent vaccine). It is also disclosed who won the 40% and who won the 60% market share.

**Conclusion**
The outcome of the tenders is made public through http://ted.europa.eu/TED/, early in the year in which the contract starts. Tender contracts typically last for 4 years. Currently, two manufacturers that produce conventional trivalent vaccine are chosen, and they get 40% and 60% of the market share each. The next tender will be released at the end of 2018. The tender contents may change as quadrivalent vaccine will be considered.
GPs receive multiple influenza vaccine deliveries a year. It is not known beforehand which vaccine will be in each delivery, unless they express a preference at the time they place the order.

## Estonia

Influenza vaccination is not included in to the National immunization programme. There is no governmental procurement of influenza vaccine in Estonia.

All people have to pay for influenza vaccination by themselves. Sometimes the employer pays for vaccination of workers.

Vaccination coverage by Influenza vaccination in Estonia is the lowest in EU (2-3%).

## Finland

Thursday November 9th, 2017. 11.00-11.35
*Finland: Hanna Nohynek (THL)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Finland, approximately 1.57 million doses of influenza vaccine are distributed through the national influenza vaccination program, vs. 200 thousand doses are sold commercially. The majority of vaccines are administered by GPs, some doses are distributed to hospital outpatients, temporary vaccination clinics or pharmacies. Private practices and occupational health obtain vaccines commercially. The influenza vaccination program including vaccine administration is funded by government. This year, the national program uses TIV whereas privately purchased vaccine is QIV.

**Topic 2 – Organization of the procurement of influenza vaccines**
A tender is used at national level. The tender is for a 2-year contract with 2 optional years. It varies whether or not the optional years are used. In the past, the tender resulted in the procurement of vaccines from two different manufacturers (in case of supply problems). However, currently one vaccine brand is procured for use in the adult population. THL organizes the logistics of the tender and distribution. Tender is awarded based on price.
If only one vaccine brand is available for a vaccine type of interest, such as live attenuated vaccine for use in children of 2 years of age, then the vaccine will be purchased directly from the manufacturer without a tendering process.

In Finland in 2017, exceptionally two brands of TIV were purchased. This occurred after a new

communicable disease act, which expects healthcare workers to be receive influenza vaccine, was implemented and increased an unexpected increase in demand was foreseen.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
The tender is published on http://ted.europa.eu in Q4 of the year prior to the season for which the influenza vaccine are procured. The tender is awarded in Q1.
So far, THL has advised October/November for the start of the seasonal vaccination, however as of 2018 the will be moved up to September/October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The volume is increasing over the years.
All manufacturers available in the EU are considered. One vaccine brand is procured for your children (live attenuated) and one for the rest (conventional trivalent or quadrivalent).

**Topic 5 - Influenza vaccine distribution**
Distribution has been outsourced to one company. This year a population-based approach will be taken, where big population centers will receive flu vaccine first.
THL makes the shipment plan, and gives this as an order to the company taking care of the national distribution. Once the vaccines reach the pharmacy of the health center / hospital district in charge, it is the municipality´s responsibility to take care of the distributions logistics from there.

This year, with two brands of TIV, the originally tendered vaccine was distributed first; the additional TIV doses were distributed only starting mid-November.

**Topic 6 - Sources of information on procured vaccines**
The tender and the tender results are available on http://ted.europa.eu.

**Conclusion**
In Finland, there is a national tender which results in the choice of 1 single vaccine that is used for all (except very young children for whom a different brand is used) in the national influenza vaccination program. Therefore, once the results of the tender are known, the vaccine that will be used at clinical sites is known. The tender period is 2 years, with an additional 2 optional years. Tender results are published on http://ted.europa.eu.

## France

Written survey received Friday November 17th.
*France: Helene Bricout (Sanofi)*
*Interviewer: not applicable*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In the France, 94% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority of vaccines are administered by GPs (95%). Others are nurses, pharmacists (pilot in pharmacy in some regions this year, so very few) and very few at hospitals. Vaccination is payed for by the national health insurance. Patients who fall under the influenza vaccine recommendations receive a voucher from the national health insurance the patient then goes to the pharmacy to pick up the vaccine, and then to a GP/nurse for administration. Patients at one GP clinics are free to choose their pharmacy (and vice versa), so GP clinics are served by more than one pharmacy.

**Topic 2 – Organization of the procurement of influenza vaccines**
Direct purchase from the manufacturers takes place annually by pharmacies. This can be individual pharmacies or groups of pharmacies. Pharmacies forecast the required volume and decide which

vaccines will be used at clinical level. GPs who administer the influenza vaccine do not control the brand distributed at pharmacy level.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Volume is forecasted in December of the previous year; which results in a pre-booking by the pharmacies. In May-June, a final booking is placed. Vaccination starts at the beginning of October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
There is no notable variability in the total required volume or brand availability. On average and currently 2 manufacturers supply influenza (next year there will be 3). On average and currently 3 vaccine brands are available, of 2 vaccine types (two classical TIVs and 1 LAIV, although the latter is hardly used in practice). This may change in the future. Pharmacies can buy different vaccine brands if they want to.

**Topic 5 - Influenza vaccine distribution**
First, vaccine is distributed to the pharmacy from the vaccine manufacturers. Then, the vaccine is delivered to the patients by the pharmacists. Finally, the vaccine is administered by a GP or a nurse.

Pharmacists hold information on which vaccines are available at the clinical site. Vaccine are distributed to the pharmacies at the beginning of September.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds brand, volume and batch information at pharmacy level, from sales data, which is held in internal system. The pharmacies also hold brand, volume and batch information.

**Conclusion**
Vaccine manufacturers sell influenza vaccines directly to pharmacies. A pre-booking is done in December, so by this time the vaccine brand(s) used at pharmacy level in the next season is/are known. However, a pharmacy may stock more than one brand, and there is no link between the pharmacy and the clinic where the vaccine is administered.

## Germany

Friday December 1st, 10.00-10.45
*Germany: Frank Eberlein (Seqirus)*
*Interviewer: Anke Stuurman*
*Also present: Mendel Haag*

**Topic 1 - Organization of the national influenza vaccination program**
In Germany, approximately 5% of the market is commercial and this includes occupational health vaccination. The major part are vaccinations for groups according to the STIKO recommendation where vaccines are reimbursed by the statutory or private health insurance (pharmacies receive reimbursement).
GPs administer close to 100% of the vaccines, a very small percentage is administered through public health institutes (health centres).

**Topic 2 - Organization of the procurement of influenza vaccines**
The influenza vaccine procurement system in Germany will change as of next year. Up to now, procurement was done through tenders, however tenders will no longer be allowed as of next year. The situation described here is the procurement situation expected as of next year.
The purchase of influenza vaccines is decentralized. For the largest part, vaccines are purchased from manufacturer by wholesalers, who sell vaccines to pharmacies. There are 6-7 major wholesalers. Other constructions do exist, for example some pharmacies purchase vaccines directly

from the manufacturer; and 4-5 large pharmacies act as wholesalers and sell the vaccine to smaller pharmacies. Pharmacies then distribute the vaccine to GPs around the pharmacy. Pharmacies consult GPs prior to ordering the vaccines. From season 2018/19 on most GPs will prefer a particular brand as GPs get back prescription responsibility due to prohibition of tenders.

**Topic 3 -Timing and stages of the influenza vaccine procurement**
Pre-orders mainly take place between February and May. As of next year 70-80% of the volume is expected to be ordered at this time. Extra orders may be placed later in case of an increase in demand.

The majority of GPs start vaccination late September/early October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The total flu vaccine market has been declining since 2009 pandemic, still declining with 1-2% annually.
As of next year, QIV will be exclusively recommended so the brand landscape will change.
There are currently four manufacturers that supply influenza vaccine in Germany . Currently 7 brands are available, including TIV, QIV, adjuvanted and live attenuated vaccines.
It is possible vaccine brands will vary from region to region under the new procurement system, depending on regional sick fund recommendations. However, this remains to be seen.

**Topic 5 - Influenza vaccine distribution**
Vaccines are distributed from the manufacturer to the wholesaler at the end of July, and soon thereafter to the pharmacies. Vaccines are distributed from the pharmacies to the GPs late August/early September.

**Topic 6 - Sources of information on procured vaccine(s)**
Pharmacies and GPs are the only ones that hold information on vaccine brands used at physician level. Manufacturers and wholesalers have information up to pharmacy level.
The outcomes of the procurement processes are not made public.

**Conclusion**
In Germany, most vaccines are administered by GPs. The system for influenza vaccine procurement will change as of next year, moving from a tender-based system to a new procurement model (details remain to be seen). In general, manufacturers sell vaccines to wholesalers (who then sell it to pharmacies) or to pharmacies directly. Pharmacies distribute the vaccines to GP clinics. Pre-orders are generally placed between February and May, so by this time it will be known which brands will be available at pharmacy level. Choice of vaccine types and brands ordered by pharmacists can be influenced by GP preference and by, for economic reasons, by pressure from the sick funds.

## Greece

Friday October 20th, 2017. 10.00-11.00
*Greece: Maura Cambiaggi (Seqirus)*
*Interviewer: Mendel Haag*
*Also present: Anke Stuurman, Caterina Rizzo (ISS)*

**Topic 1 - Organization of the national influenza vaccination program**
A national influenza vaccination program is in place in Greece for elderly and risk groups.
The GPs prescribe the influenza vaccines, the patient retrieves the vaccine from the pharmacy and return to the GP for the administration of the vaccine
Influenza vaccines are “listed” products for which the pricing is set by the government – the

government pays for the vaccination.

**Topic 2 - Organization of the procurement of influenza vaccines**
The purchase of the influenza vaccines for the Greece national vaccination program is decentralized; primarily through whole salers purchase from manufacturers (90%), and subsequent resale from whole salers to pharmacies. Direct to pharmacy sale is also possible, but limited.
In addition, there is a small proportion purchased by the government for the immigrants and the poor.
There are no notable other procurement channels or separate procurement channels for hospitals etc.
There is no forecast at the national level of the number of doses needed. Purchased volumes are determined by the whole salers.

There are around 50 whole salers.
There is no apparent organization of the whole salers by geographical region, as such there is no geographical organization of vaccine procurement.

The whole salers solicit bids from the manufacturers who can each submit their offer.
The purchase orders are issued annually.

**Topic 3 - Timing and stages of the influenza vaccine procurement**
Pre-orders may be booked in March, but otherwise the vaccine procurement starts in September.
Vaccines are distributed towards end of Sept – early Oct. The campaign starts end of October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
There is no specific classification in the vaccine procurement according to type of vaccine or brand, there are no preferred suppliers.
There is a mix of vaccine brands available.
Though differentiation by vaccine type is present, it is has been more limited since to the social economic crisis in Greece.

**Topic 5 - Influenza vaccine distribution**
The vaccine distribution are the responsibility of the manufacturer and whole salers.

**Topic 6 - Sources of information on procured vaccine(s)**
The whole salers are the holders of the information of which pharmacies have which vaccine available.
The MAH only hold information on which whole salers purchase the vaccines.

## Italy

Tuesday October 31st, 2017. 16.30-18.00
*Italy: Maura Cambiaggi (Seqirus), Caterina Rizzo (ISS)*
*Interviewer: Anke Stuurman, Mendel Haag*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Italy, approximately 95% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority of vaccines are administered by GPs, although some are administered at vaccination clinics or by paediatricians. Risk groups can choose whom they get their vaccine from. The influenza vaccination program is funded by regional government.

**Topic 2 – Organization of the procurement of influenza vaccines**
Tenders are issued at regional level. There are 20 regions. Most have an annual tender, although 2 regions have 3 year tenders and 2 or 3 regions have 2 year tenders. There may be variations between

regions. However, generally each tender contains information on the volume of vaccines required per type for that region. Forecasting of required volume is done by the Department of Prevention in each region. The regional government is responsible for the tenders. There is a separate purchase unit. For example, in Tuscany the regional department of health is consulted by the regional vaccination committee for the contents of the tender. The tender is issued by ESTAR, an administrative body of the regional government. The GPs obtain the vaccine from the regional health system, there is no prescription. The GP received a fee (from the region) for vaccine administration.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Timing of all stages of the tender varies between regions. Generally, volume forecasting takes place between March/April and September. Tenders are issued between May/June and September/October. Tenders are awarded within 2 weeks to 2 months. In theory, upon tender award, it is known at clinical level which vaccines brands are available. The timing when vaccines are distributed to the clinical sites in relation to the start of vaccination depends on their storage capacities. The start of the seasonal vaccination varies between regions and between clinics, depending on their priorities.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
All influenza vaccine manufacturers that are active in Europe are considered for the tender. There is no pre-specified minimum or maximum. Each year on average at least 6 vaccine brands are available. Four of these are historically always present. The quantities required by vaccine type are pre-specified in the tender. All vaccine types are available.
Generally, 2 brands of TIV are procured per region, 2 brands of QIV, 1 brand of a-TIV and 1 intradermal. Cell-based or nasal vaccines are not available for the national vaccination program. Sometimes there is shortage of one brand, in which case another brand is used.

**Topic 5 - Influenza vaccine distribution**
Vaccine is usually delivered to 3rd party distribution warehouses. The company gets an order from the customer ("sold to": regional government or local health unit), they generate a delivery note to the warehouse to deliver to customer ("ship to": local health unit or districts). A 3rd party cold chain logistics company ships to clinic.
The manufacturer and the 3$^{rd}$ party warehouse do not necessarily hold information on which vaccines are available at clinical site level (i.e. individual general practitioner). There are few warehouses, and 2-3 cold chain logistics parties.
In each region only 1 vaccine brand wins per type, but that still doesn't tell you which type of vaccine is administered somewhere.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds data on the where the vaccines are at local health unit level; through tender and customer orders, but not necessarily on the general practitioner level. Some vaccine tender organizations are well organized (others are not) and hold electronic information on the procured vaccines. The national public health institute likely knows which type of vaccine is administered (after administration), as this information is used to estimate vaccine coverage (to be confirmed by authority). The warehouse knows where the vaccine is shipped to. Regulatory agency collect information on which vaccine is distributed and where.
In theory, the outcome of the vaccine procurement process is public. In practice, it's not easy to find this information on web pages of regions. There is always an official document as soon as the tender has been awarded. The manufacturers also hold information on the tender outcome.
If the IMS report is accurate, this could capture brand data.

**Conclusion**
The outcome of the regional tenders may be easiest to obtain through the market authorization holders (MAH) – unless the central government receives the outcome of the regional tenders with relatively little delay. Depending on who issues the order, the MAH may or may not know which

vaccine brands are available at clinic level. Given the short time between the distribution and the start of the campaign, distribution data appears to have no additional value.

## Netherlands

Monday November 20th, 2017. 14.00-14.40.
*Netherlands: Sjirk Kok (RIVM)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In the Netherlands, approximately 97-98% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority of vaccines are administered by GPs (97%, >5000 GPs), all risk groups receive an influenza vaccination invitation letter from their GP. A minority is administered at long term care facilities (2-3%, about 200 homes). The influenza vaccination program including vaccine administration is funded by government.

**Topic 2 – Organization of the procurement of influenza vaccines**
A tender is used at national level for conventional trivalent vaccine. The tender is for a 1-year contract with 3 optional years. Usually the optional years are used, unless there is a change in the influenza vaccination program. Two different manufacturers are chosen, one obtains 1/3rd of the market share, the other 2/3rds.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
The tender is published on www.tenderned.nl in August and closes in October of the year prior to the start of the contract. In 2015, the tender was awarded in November. A provisional order is placed in January/February. The final order is placed in May.
Vaccine deliveries to GPs start in week 38. Typically, GPs receive 2-4 deliveries a year (pre-delivery for early vaccination, main delivery with largest bulk of vaccines, 1 or 2 final deliveries in case main delivery insufficient). The GPs only know which vaccine brand they will use once they receive a delivery. The vaccine brand can change with each delivery (the two trivalent vaccines are seen as interchangeable). Most vaccination takes places in October-November.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The volume ordered every year is relatively stable (1-2% decrease every year). Brand availability is stable throughout the tendered contract (1-4 years).
All manufacturers that have an influenza vaccine registered in the Netherlands are invited to participate in the tender (see CBG website for details). Two brands of conventional trivalent vaccine are chosen.. No other vaccine types are considered.

**Topic 5 - Influenza vaccine distribution**
RIVM buys vaccines from manufacturers through a tender. Warehousing has been outsourced to Movianto (located in Oss) for all influenza and national vaccination program vaccines. Orders from GPs come in through the SNPG platform (https://www.snpg.nl/over-snpg/). Consequently, Movianto arranges distribution of vaccines to GPs.
Deliveries start in week 38, each GP receives multiple deliveries throughout the season.

**Topic 6 - Sources of information on procured vaccines**
The RIVM holds data on brand, volume and batch at national and GP level. However, the latter is only known to the RIVM once the invoice has been received (in case of a vaccine recall, this data can be accessed through Movianto).
The outcome of the vaccine tender is made public on www.tenderned.nl, where the tender is also posted. In 2015, the outcome of the tender was posted in December. This includes the name of the two chosen manufacturers but not the vaccine brand (although this can easily be deduced as it's

always conventional trivalent vaccine) and it is not disclosed who won the 1/3 market share vs the 2/3 market share.

**Conclusion**
The outcome of the tenders can be obtained through www.tenderned.nl, in December of the year prior to the start of the contract. Tender contracts last for 1 year + 3 optional years. Usually the optional years are used unless there is a change in the influenza vaccination program. Two manufacturers who produce conventional trivalent vaccine are chosen, who get 1/3rd and 2/3rds of the market share. GPs receive 2-4 influenza vaccine deliveries a year. It is not known beforehand which vaccine will be in each delivery (vaccines are considered interchangeable).

## Norway

Wednesday November 29th, 2017. 14.15-14.45.
*Norway: Knut Jønsrud (Norwegian Institute of Public Health)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Norway, approximately 90% of the influenza vaccines are provided under the national influenza vaccine program. They are administered by GPs, at hospitals (in and outpatients), and at vaccination clinics.
The vaccine recipient pays. However, risk groups pay the tendered vaccine price which is about 50% lower than the market price.

**Topic 2 – Organization of the procurement of influenza vaccines**
A tender is used at national level for procurement of trivalent vaccine. The tender is for a 2 year contract with twice one optional year. Two different manufacturers are chosen, both obtain approximately half of the total tendered volume. The tender is issued and managed by the NIPH.
Most likely the next tender will be for the influenza season 2019-2010; QIV will be considered.
In practice volume forecasts are done by the NIPH, this takes place in spring.
Nasal vaccine is purchased directly from the manufacturer.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
The month in which the tender is issued (and published on http://ted.europa.eu/ ) and awarded can change depending on the year and the previous contract. Bookings needs to be sent to the manufacturers by approximately April-May.
An electronic webportal is used through which clinics can order vaccines from the NPHI. Clinics are told which of the 2 vaccine brands to order depending on the region they are in. Next year, the aim is to have clinics order their vaccines (and therefore know the brand used at their clinic) before May.
Vaccination starts in October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The season the volume of distributed vaccines was much larger than in previous years.
The available brands can change with every tender.
Three manufacturers are considered for TIV and one for nasal vaccine. In the next tender QIV will be considered..

**Topic 5 - Influenza vaccine distribution**
NIPH is responsible for the distribution of vaccines (through contract partners) to municipalities and hospitals. Municipalities are responsible for organization distribution to clinics.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds data on the vaccines sold to NIPH.

NIPH holds data on vaccines ordered by clinics, and on vaccines distributed up to municipality level. The entire tender process is public except for the unit price (manufacturer, type, brand, and maximum tendered volume) from http://ted.europa.eu/.

**Conclusion**
In Norway, influenza vaccines are procured through a national tender. Tenders are for 2-year contracts, plus twice one optional year. Two TIV brands are procured, each manufacturer gets about 50% of the tender. In the next tender, QIV will be considered. As of next year, clinics will have to order their vaccines from the NPHI by May, and the clinics will be told which brand to order based on the geographic region in which they are located. Therefore, they will know what brand will be used at their clinic by May latest. Tenders and tender results are available on the http://ted.europa.eu website.

## Slovenia

Wednesday November 29th, 2017. 10.00-10.45
*Slovenia: Staša Javornik (National Public Health Institute, NPHI)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Slovenia, all influenza vaccines are procured through the NPHI. Of these 70% are provided to risk groups and 30% to non-risk groups. Vaccines are administered by GPs (70%), hospitals (inpatients and employees, 13%) and by the public health institute (18%). Recipients are free to choose the health care provider for receipt of vaccine with no impact on reimbursement (GPs or NIPH).
For risk groups, the vaccine is paid for by the national health insurance (Health Insurance Institute of Slovenia), but the vaccine recipient has to pay for vaccination. The NPHI is working on a plan to also reimburse vaccination. Non-risk groups have to pay for the vaccine and for vaccination.

**Topic 2 – Organization of the procurement of influenza vaccines**
A tender is used at national level on an annual basis by the NPHI. One tender is issued, separated into lots (one for children <3 years, and one for all other age groups). One vaccine brand is procured per lot. In case of an unforeseen increase in demand, an additional tender may be issued. The last time this happened was in 2005, during the bird flu outbreaks.
The Ministry of Health confirm and issue the annual vaccination program, after Health Insurance Institute of Slovenia ensures funding.
After the end of the influenza season (end of February), the NPHI ask the healthcare providers how many doses of influenza vaccine they will need for the next season. The tender is issued and managed by the NPHI. The national advisory committee on immunization gives advice on the tender content (for example: type of vaccine, award criteria).

**Topic 3 – Timing and stages of the influenza vaccine procurement**
The tender is published in March. The tender is awarded in April and the contract is concluded in April-May.
Vaccines are distributed to the healthcare providers in the first two weeks of October. Vaccination can start as soon as vaccines are received.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
The volume of distributed influenza vaccine has decreased of the past years, however it increased again this year. It is difficult to predict future volume based on historical data.
All manufacturers with a marketing authorization license in Slovenia are considered. One vaccine brand is procured for children <3 years (trivalent) and one for the rest (quadrivalent). Selected brands can change with every tender. A pediatric TIV is used for children <3 years, and a QIV is used for other age groups.

**Topic 5 - Influenza vaccine distribution**
The NPHI buys vaccines from the manufacturer. NPHI has a wholesaler license and therefore also distributed the vaccine to health centres that administer the vaccine.

NPHI has a computerized tracking system to track the serial batch numbers distributed to each center.

In case more than one brand would be available for one age group (e.g. as in 2005), the vaccines are allocated 'randomly'. GPs cannot choose the brand.

**Topic 6 - Sources of information on procured vaccines**
The manufacture holds information on the vaccine brands and volume sold to NPHI at national level. NPHI holds information on vaccine brand and volume at clinic level.
The tender and the tender results are available on the following website: https://www.enarocanje.si/ . This contains the name of the manufacturer and total price. Information on procured vaccines through framework agreement is updated every 3 months.
Information about vaccine against flu available in Slovenia are on the following website: http://www.nijz.si/sl/cepiva-proti-posameznim-boleznim-gripa
Information on procured vaccines is also available upon request from NPHI.

**Conclusion**
In Slovenia, all influenza vaccines are procured through a national tender. Vaccines are administered by GPs and the public health institute. Tenders are issued on an annual basis and are awarded in April. The tender is split into lots (children <3 years, the rest). One brand of trivalent vaccine is procured for children <3 years and quadrivalent vaccine is procured for the rest. Tenders and tender results are available on the following website: https://www.enarocanje.si/. All information is publicly available from NPHI upon request.

## Spain

Wednesday December 13th, 2017. 07:30-09:00
*Spain: Toni Lloret (Seqirus),*
*Interview: Mendel Haag*

Wednesday December 13th, 2017. 11:30-12:00
*Spain: Javier Diez-Domingo (FISABIO),*
*Interview: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Spain, approximately 95% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority of vaccines are administered by GPs. Risk groups can choose whom they get their vaccine from. The influenza vaccination program is funded by regional government.

**Topic 2 – Organization of the procurement of influenza vaccines**
Tenders are issued at national and at regional level, regions can choose whether they want to participate in the national tender (issued by the Ministry of Health) or issue their own tender. There are 17 regions in Spain, around 8 issue regional tenders (especially the larger regions). Multiple vaccine brands per type are procured through the national tender, each region negotiates a price for the brands they want.

Most have an annual tender, although 2 regions have 2 year tenders.

There may be variations between regions. However, generally each tender contains information on

the volume of vaccines required per type for that region. Forecasting of required volume is done by the Public Health Department in each region. The regional government is responsible for the tenders.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Timing of all stages of the tender varies between regions. Generally, volume forecasting takes place between March/April and September, and is based on last year's vaccine coverage. Tenders are issued between May and September/October. Tenders are awarded within 2 weeks to 2 months. In Valencia, tenders are generally issued May-July and awarded at the end of July, although this year the tender was awarded mid-September.
In theory, upon tender award, it is known at clinical level which vaccines brands are available. The timing when vaccines are distributed to the clinical sites in relation to the start of vaccination depends on their storage capacities. The start of the seasonal vaccination varies between regions and between clinics, depending on their priorities but is generally in October.
Last year regions agreed to start the campaign mid October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
All influenza vaccine manufacturers that are active in Europe are considered for the tender (. There is no pre-specified minimum or maximum. Each year on average at least 5 vaccine brands are available. Four of these are historically always present. The quantities required by vaccine type are pre-specified in the tender. All vaccine types are available.
Generally, 2 brands of TIV are procured per region, 2 brands of QIV, 1 brand of aTIV and 1 intradermal. In the national tender, generally 2-3 brands of TIV and 1-2 brands of TIV are procured. Cell-based is not available and nasal vaccine has been withdrawal from the market.
In certain regions there is a recommendation for adjuvanted vaccines for those aged 65 years and above.

**Topic 5 - Influenza vaccine distribution**
Vaccine is usually delivered to 3rd party distribution warehouses. The company gets an order from the customer ("sold to": regional government), they generate a delivery note to the warehouse to deliver to customer ("ship to": local health unit or districts). A 3rd party cold chain logistics company ships to clinic.
The manufacturer and the 3rd party warehouse do not necessarily hold information on which vaccines are available at clinical site level (i.e. individual general practitioner). There are few warehouses, and 2-3 cold chain logistics parties.
In each region only 1 vaccine brand wins per type (although there are exception as some regions choose 2 conventional TIV), but that still doesn't tell you which type of vaccine is administered somewhere.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds data on the where the vaccines are at local health unit level; through tender and customer orders, but not necessarily on the general practitioner level. Some vaccine tender organizations are well organized (other are not) and hold electronic information on the procured vaccines. The national public health institute likely knows which type of vaccine is administered (after administration), as this information is used to estimate vaccine coverage (to be confirmed by authority). The warehouse knows where the vaccine is shipped to. Regulatory agency has to release each batch and collect information on which vaccine is distributed and where.
The outcome of the vaccine procurement process is public. There is always an official document as soon as the tender has been awarded and the contract between parties have been signed. The manufacturers also hold information on the tender outcome.

**Conclusion**
The outcome of the regional tenders may be easiest to obtain through the market authorization holders (MAH) – unless the central government receives the outcome of the regional tenders with relatively little delay. Depending on who issues the order, the MAH may or may not know which

vaccine brands are available at clinic level. Given the short time between the distribution and the start of the campaign, distribution data appears to have no additional value.

## Sweden

Written survey received Tuesday November 20th.
*France: Helene Bricout (Sanofi)*
*Interviewer: not applicable*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In Sweden, more than 95% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority (>95%) are administered by permanent vaccination clinics. Risk groups are free to choose the vaccination clinic they will attend to receive the vaccination, with no impact on reimbursement. The influenza vaccination program is funded by regional government.

**Topic 2 – Organization of the procurement of influenza vaccines**
Tenders are issued at regional level. There are 10 regions. Typically, tenders are issues every 4 years, resulting in approximately 2-3 regional tenders per year throughout Sweden. It's generally a one lot tender per region. Regional tender organizations are in charge of volume forecasting, issuing and managing tenders, and awarding the tender.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Tenders are issue 9-12 months ahead of the first season, in this time frame booking are done. Seasonal vaccination starts at the end of October or the beginning of November.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
There is no notable variability in the historical tendered volume. Brands change according to the tender award. On average, there are 3 manufacturers (currently there are 2) that provide influenza vaccine. Currently two brands of classical TIV are available. Quadrivalent vaccine may be considered next year.

**Topic 5 - Influenza vaccine distribution**
Vaccines are distributed directly from the manufacturer to each local vaccination clinic. Vaccines are distributed to the vaccination clinics in September.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds brand, volume and batch data at national, regional and clinic level (internal database). Vaccine clinics hold brand, volume and batch data at clinic level (internal database).
Manufacturers, types, brands and volume are publicly available (from tender and tender award) through regional tender organization 9-12 months ahead of the season.

**Conclusion**
Vaccines are administered at vaccination clinics. Influenza vaccine is purchased through regional tenders (10 regions), contracts typically run for 4 years. The tender outcome is generally publicly available 9-12 months prior to the season. Regional tenders are generally for one lot. Therefore, vaccine brand administered at clinic level is known well ahead of the season (also in tender years).

## UK

Tuesday November 21st, 2017.
*UK: Paul Kenny (GSK)*
*Interviewer: Anke Stuurman*

**Topic 1 – Organization of the national influenza vaccination program (administration)**
In the UK, 95% of the influenza vaccines are provided under the national influenza vaccine program. The vast majority of vaccines are administered by GPs, including through vaccination clinics organized by GPs. Some vaccination takes place at retail pharmacies, hospitals and schools. Patients are free to choose whether to get the vaccine at their own GP or at a retail pharmacy, this has no impact on reimbursement. Influenza vaccine is funded by the government

**Topic 2 – Organization of the procurement of influenza vaccines**
Most vaccines are purchased directly from the manufacturers by GPs; these are then reimbursed to the GPs by the NHS. GPs forecast the required volume and decide on the brand vaccine to be used at their clinic. Vaccines are procured annually.
Some government tenders exist, e.g. in Scotland, for healthcare workers, and for intra-nasal vaccine for children; but in total this accounts for <20% of administered vaccines <20%.
There are some but very few wholesalers.

**Topic 3 – Timing and stages of the influenza vaccine procurement**
Volume forecasts are done in Q4 of the previous year or Q1, this is also when pre-bookings are placed. Final orders are placed in Q2.
As GPs purchase vaccine directly from the manufacturer, they know at the time of ordering (Q4-Q1) which brands will be available at their clinic the next season.
Vaccination typically starts in the second half of September and continues throughout October.

**Topic 4 - Variability and diversity of volume and type of influenza vaccine**
Generally, the total volume is stable. There is an increase in the number of intranasal vaccine doses as more cohorts of children are added every year.
Five manufacturers currently sell influenza vaccines in the UK, resulting in 8 brands and 3 vaccine types (TIV, QIV and intra nasal vaccine).
There is a government tender for intra-nasal vaccine, where the government provides intra-nasal vaccine to the GPs free of charge.
Unclear how many vaccine brands and types GPs buy. Probably from one manufacturer and only either TIV or QIV, but not certain.

**Topic 5 - Influenza vaccine distribution**
The first doses of vaccine are distributed in the first half of September.

**Topic 6 - Sources of information on procured vaccines**
The manufacturer holds brand, volume and batch information at GP level, from direct sales data.

**Conclusion**
Overall, most vaccines are administered by GPs and GPs purchase vaccines directly from the manufacturer (although there are some tenders and wholesalers). A pre-booking is done in Q4/Q1, so by this time the vaccine brand(s) used in the next season is/are known.

# 13.Annex 4 – Competition law

Overall, most vaccines are administered by GPs and GPs purchase vaccines directly from the manufacturer (although there are some tenders and wholesalers). A pre-booking is done in Q4/Q1, so by this time the vaccine brand(s) used in the next season is/are known.

**Article 101 TFEU and equivalent provisions of national legislations**

Article 101 of the Treaty on the Functioning of the European Union (TFEU) and the equivalent national legislation of EU Member States prohibits agreements that have as their object or effect the restriction, prevention or distortion of competition.

Information exchange is a common feature of many competitive markets and may generate various types of efficiency gains. However, the exchange of market information may also lead to restrictions of competition in particular in situations where it is liable to enable undertakings to be aware of market strategies of their competitors. The competitive outcome of information exchange depends on the characteristics of the market in which it takes place (such as concentration, transparency, stability, symmetry, complexity etc.) as well as on the type of information that is exchanged, which may modify the relevant market environment towards one liable to coordination.

**Restriction of competition by object**

Exchanging information on companies' individualised intentions concerning future conduct regarding prices or quantities is particularly likely to lead to a collusive outcome. Informing each other about such intentions may allow competitors to arrive at a common higher price level without incurring the risk of losing market share or triggering a price war during the period of adjustment to new prices. Moreover, it is less likely that information exchanges concerning future intentions are made for pro-competitive reasons than exchanges of actual data. Information exchanges between competitors of individualised data regarding intended future prices or quantities should therefore be considered a restriction of competition by object. In addition, private exchanges between competitors of their individualised intentions regarding future prices or quantities would normally be considered and fined as cartels because they generally have the object of fixing prices or quantities. Information exchanges that constitute cartels not only infringe Article 101(1), but, in addition, are very unlikely to fulfil the conditions of Article 101(3).

**Restrictive effects on competition**

The likely effects of an information exchange on competition must be analysed on a case-by-case basis as the results of the assessment depend on a combination of various case specific factors. The assessment of restrictive effects on competition compares the likely effects of the information exchange with the competitive situation that would prevail in the absence of that specific information exchange. For an information exchange to have restrictive effects on competition within the meaning of Article 101(1), it must be likely to have an appreciable adverse impact on one (or several) of the parameters of competition such as price, output, product quality, product variety or innovation. Whether or not an exchange of information will have restrictive effects on competition depends on both the economic conditions on the relevant markets and the characteristics of information exchanged.

*(i) Market characteristics:*

Companies are more likely to achieve a collusive outcome in markets which are sufficiently transparent, concentrated, non-complex, stable and symmetric. In those types of markets companies can reach a common understanding on the terms of coordination and successfully monitor and punish deviations. However, information exchange can also enable companies to achieve a collusive outcome in other market situations where they would not be able to do so in the absence of the information exchange. Information exchange can thereby facilitate a collusive outcome by increasing transparency in the market, reducing market complexity, buffering instability or compensating for asymmetry. In this context, the competitive outcome of an information exchange depends not only on the initial characteristics of the market in which it takes place (such as concentration, transparency, stability, complexity etc.), but also on how the type of the information exchanged may change those characteristics. Tight oligopolies can facilitate a collusive outcome on the market as it is

easier for fewer companies to reach a common understanding on the terms of coordination and to monitor deviations. A collusive outcome is also more likely to be sustainable with fewer companies. With more companies coordinating, the gains from deviating are greater because a larger market share can be gained through undercutting.

*(ii) Characteristics of the information exchange:*

The exchange between competitors of strategic data, that is to say, data that reduces strategic uncertainty in the market, is more likely to be caught by Article 101 than exchanges of other types of information. Sharing of strategic data can give rise to restrictive effects on competition because it reduces the parties' decision-making independence by decreasing their incentives to compete. Strategic information can be related to prices (for example, actual prices, discounts, increases, reductions or rebates), customer lists, production costs, quantities, turnovers, sales, capacities, qualities, marketing plans, risks, investments, technologies and R&D programmes and their results. Generally, information related to prices and quantities is the most strategic, followed by information about costs and demand. However, if companies compete with regard to R&D it is the technology data that may be the most strategic for competition. The strategic usefulness of data also depends on its aggregation and age, as well as the market context and frequency of the exchange. Exchanges of genuinely aggregated data, that is to say, where the recognition of individualised company level information is sufficiently difficult, are much less likely to lead to restrictive effects on competition than exchanges of company level data. Collection and publication of aggregated market data (such as sales data, data on capacities or data on costs of inputs and components) by a trade organisation or market intelligence firm may benefit suppliers and customers alike by allowing them to get a clearer picture of the economic situation of a sector. Such data collection and publication may allow market participants to make better-informed individual choices in order to adapt efficiently their strategy to the market conditions.

The exchange of historic data is unlikely to lead to a collusive outcome as it is unlikely to be indicative of the competitors' future conduct or to provide a common understanding on the market. Moreover, exchanging historic data is unlikely to facilitate monitoring of deviations because the older the data, the less useful it would be for timely detection of deviations and thus as a credible threat of prompt retaliation . There is no predetermined threshold when data becomes historic, that is to say, old enough not to pose risks to competition. Whether data is genuinely historic depends on the specific characteristics of the relevant market and in particular the frequency of price re-negotiations in the industry. Moreover, the threshold when data becomes historic also depends on the data's nature, aggregation, frequency of the exchange, and the characteristics of the relevant market (for example, its stability and transparency).

Frequent exchanges of information that facilitate both a better common understanding of the market and monitoring of deviations increase the risks of a collusive outcome. In more unstable markets, more frequent exchanges of information may be necessary to facilitate a collusive outcome than in stable markets. In markets with long-term contracts (which are indicative of infrequent price re-negotiations) a less frequent exchange of information would normally be sufficient to achieve a collusive outcome. By contrast, infrequent exchanges would not tend to be sufficient to achieve a collusive outcome in markets with short-term contracts indicative of frequent price re-negotiations. However, the frequency at which data needs to be exchanged to facilitate a collusive outcome also depends on the nature, age and aggregation of data.In general, exchanges of genuinely public information are unlikely to constitute an infringement of Article 101 . Genuinely public information is information that is generally equally accessible (in terms of costs of access) to all competitors and customers. For information to be genuinely public, obtaining it should not be more costly for customers and companies unaffiliated to the exchange system than for the companies exchanging the information.