



# GUIDELINES TO MEASURE EXPENDITURE ON OVER-THE- COUNTER (OTC) DRUGS

December 2012

Contact [SHA.Contact@oecd.org](mailto:SHA.Contact@oecd.org)



Health Division

[www.oecd.org/health](http://www.oecd.org/health)

Directorate for Employment, Labour and Social  
Affairs

## ACKNOWLEDGEMENTS

1. This report was prepared by Tomáš Roubal from the Czech Ministry of Health along with Roberto Astolfi and David Morgan. We would like to thank all the respondents to the questionnaire that formed the basis of this report. In particular we would express our particular thanks to the following experts who provided more detailed information:

2. Gilles Fortin (Canadian Institute for Health Information), Harles Luts (National Institute for Health Development. Estonia), M. Carmen Rodríguez Blas (Ministry of Health, Social Services and Equality, Spain), Hyoung-Sun Jeong (Yonsei Institute for Health and Welfare, Korea), Ana Cristina Ramos and Alexandra Carvalho (Statistics Portugal), Marie Glanzelius (Statistics Sweden) and Cathy Cowan (Centers for Medicare & Medicaid Services, United States).

3. Useful comments and suggestions were received from colleagues in the Health Accounts team as well from Eurostat, WHO and the participants of the 14th Meeting of National Health Account Experts.

4. This project was funded under EU contribution agreement 2011 53 01.

## TABLE OF CONTENTS

ACKNOWLEDGEMENTS .....	2
Introduction.....	4
General approach to estimating OTC drugs expenditure .....	4
Step 1: Analysis of the legal framework for the OTC drugs market in the reporting country. ....	4
Step 2: Identification of the relevant data sources.....	5
Step 3: Mapping data sources to the relevant SHA categories.....	5
Step 4: Final adjustments .....	5
Analysis of the legal framework of OTC drugs .....	6
Data sources used to measure OTC drugs expenditures .....	7
Household Budget Surveys (HBS).....	7
Final consumption expenditure of households by consumption purpose.....	7
Providers' sales .....	8
Administrative data on pharmaceutical market.....	8
Mapping of OTC drugs to the SHA framework .....	9
The SHA 2011 definition of OTC.....	9
Differences between SHA 2011 and SHA 1.0 definitions .....	9
Drugs with facultative prescription status .....	10
Country experience in mapping original data sources to the SHA categories .....	11
Final adjustments .....	11
Conclusion .....	12

### Tables

Table 1 Classification of pharmaceuticals (HC.5.1) according to SHA 1.0 and SHA 2011.....	10
---	----

## **Introduction**

5. This paper provides draft guidelines to better estimate expenditure on Over-The-Counter (OTC) drugs under the System of Health Accounts (SHA) framework. Drawing on current practices, the guidelines aim to assist countries in starting to report OTC drugs expenditures, as well as helping others to improve their current methodology. Moreover, the study seeks to enhance the exchange of experiences between countries such that the comparability, accuracy, reliability and policy relevance of pharmaceutical expenditure data can be improved.

6. The guidelines describe a general approach, consisting of four steps –national legislation, data sources, mapping into the SHA categories and adjustments to the data - complemented with further clarifications on the new definitions of OTC drugs presented in the new System of Health Accounts manual (SHA 2011) together with information on how to capture recent developments in the OTC drug market, such as the intensification of patient mobility across borders and the diffusion of on-line purchases.

7. The report is organized into seven sections. After this introduction, section two outlines the four-step general approach that countries may use to estimate expenditures on OTC drugs. Each of the steps is then dealt with in more detail. The legal framework regarding OTC drugs expenditures is elaborated in the third section. Section four analyses in details the new definitions of OTC drugs, clarifying the term “independently purchased” and tracks the changes between the two definitions of OTC drugs proposed by SHA 1.0 and SHA 2011. The fifth section focuses on types of data sources that countries currently use to estimate OTC drugs expenditure (household budget surveys, provider sales, administrative data and data from specific surveys on pharmaceutical market) while section six presents the adjustments that might be required to produce the final estimation of OTC. Section seven provides some conclusions.

### **General approach to estimating OTC drugs expenditure**

8. This section outlines a general approach to estimate expenditures on OTC drugs. The general approach may help countries that do not yet report spending estimates on OTC drugs and may also assist those countries that would like to improve their current methodology. The proposed approach consists of four steps: description of the legal framework of the OTC drugs market in the reporting country; identification of the relevant data sources; mapping data sources to the SHA boundaries and concludes with the reconciliation and final adjustments to produce accurate and consistent estimates. Each step is briefly summarised in this section with a more in-depth description of each in the following sections.

#### ***Step 1: Analysis of the legal framework for the OTC drugs market in the reporting country.***

9. An in-depth knowledge of the legislation of the pharmaceutical market is a pre-requisite to identify the relevant data sources for the estimation of OTC drugs. The pharmaceutical market in OECD countries tends to be heavily regulated both on the supply side (production, wholesale and retail sales) as well as on the demand side (requirement of prescription for the purchase of certain drugs). National legislation is often influenced by international regulations or directives. Detailed information on the legislation may allow:

- Identifying the designated administrative body (if any) in charge of determining what products are considered as pharmaceutical products and, within that, those that can be sold without a prescription. Very often, the same body is also in charge of collecting statistical information on expenditure, quantities and prices of pharmaceuticals sold.
- Clearly identify the boundaries between drugs that can be sold with a prescription and those for which the prescription is facultative or not required at all. This, in turn, permits the differentiation between pharmaceuticals, dietary supplements and other personal care products.

- Single out retailers (providers in SHA terminology) authorised to sell or distribute OTC drugs to households. The legislation may impose a reporting obligation on the retailer which can help to break down OTC drugs expenditure by providers.
- Distinguish to what extent social (insurance) systems reimburse expenditure on pharmaceuticals, including OTC drugs. This can help to break down OTC drugs expenditure by financing schemes.

Section 3 provides more detail on this first step of analysing the legislation, drawing on the experience of the countries that participated in the study.

### ***Step 2: Identification of the relevant data sources***

10. The second step is to identify the relevant data sources. Important information can be gathered through a large variety of data sources including Household Budget Survey, providers' sales information, administrative data, or by specific market surveys. Relevant information from those sources may include:

- Detailed information on products – such as classification used (e.g. Classification of Individual Consumption According to Purpose, Central Product Classification and its subclasses), listing of goods included (e.g. names of pharmaceuticals, Anatomical Therapeutic Chemical Classification), prescription status, final or intermediate use, and distinction between drugs and therapeutic appliances,
- Information on market coverage. For instance, whether only pharmacies are covered or all possible providers (such as supermarkets, internet retailers) or whether the external trade (imports and exports) is captured.
- Information on prices – whether total expenditures are included or only prices for individual products are available, information on rebates or taxes.
- Meta information on data used: frequency of the collection, representativeness, sampling coverage and data adjustment methods.

More information on data sources currently used is presented in Section 4.

### ***Step 3: Mapping data sources to the relevant SHA categories***

11. The third step aims at mapping the identified data sources into the relevant categories of the System of Health Accounts. First, an accurate mapping of raw data into the OTC drug boundaries is required (that is, distinguishing what should be included and excluded) and then to breakdown the total OTC drugs expenditure by financing schemes and providers' categories in a consistent way. Very often, information from multiple data sources is required. Many countries are able to identify information on total expenditures while a few use information on volumes and prices. More detail on mapping is provided in Section 5 of this report.

### ***Step 4: Final adjustments***

12. The last step consists of combining all available information into a consistent estimate across the categories (provider and financing schemes) for which expenditures on OTC can be disaggregated. Indirect estimation methods may be applied at this stage in the absence of specific information on OTC. Also, where detailed estimations are produced for benchmark years only, interpolation and extrapolation techniques may need to be applied for the periods in between (interpolation) and for the most recent years following the last available estimate (extrapolation). More information on reconciliation and final adjustments is provided in Section 6.

## Analysis of the legal framework of OTC drugs

13. An in-depth analysis of the legal framework of the OTC drug market is a prerequisite to accurately estimate how much a country spends on OTC drugs. Knowledge of the legal framework allows the identification of:

- i. which pharmaceutical *products* require a prescription;
- ii. which *authority* is the decision-making body in this respect and whether such an authority collects statistical information that could be used by the SHA national compiler;
- iii. which *vendors* are authorised to sell OTC drugs (health care providers) and whether they have any reporting obligation;
- iv. to what extent and under what circumstances *reimbursement* on OTC drugs are possible (financing schemes);
- v. *illegal sales* of OTC drugs that should also be reported under the SHA framework.

This section offers some insight into the fundamental elements of the legal framework that can help SHA compilers when estimating OTC within the general approach process.

14. The national legislation differentiates pharmaceutical products from any other product and within those, those drugs that may be sold without a valid prescription.<sup>1</sup> National legislation specifies the requirements on market entry, testing and surveillance of drugs. It should also list drugs with their prescription status which is a decisive point in identifying OTC drugs in the classification process.

15. A national authority is specifically appointed (e.g. the Danish Health and Medicines Authority, the Food and Drug Administration in the USA, or the European medicines agency etc.) for the implementation and enforcement of regulations. Drugs are usually sold under the surveillance of these authorities and they may also gather statistical data on the market. Such data (administrative source) can be a valuable data source for the estimation of OTC drug expenditure (e.g. Estonia).

16. Legislation can also determine who is legally permitted to dispense which drugs to the public, i.e. pharmacies, drug stores, chemists, supermarkets or online retailers. It usually defines some reporting obligations that can be used in the estimation of OTC drug expenditures. Knowledge of which vendors are allowed in the country allows data compilers identifying the universe of possible providers of OTC drugs. For example, in Sweden until very recently only state-owned pharmacies were allowed to legally sell drugs. However, a reform in 2009 opened up the market allowing the presence of private pharmacies. Similarly, the reform introduced in Italy in 2006 allowed some retailers (other than pharmacies) to sell OTC. As a result, sampling methodologies need to be adjusted to accurately capture the new market conditions.

17. Rules on the reimbursement of OTC drugs could be of particular interest as it may allow countries to breakdown OTC drug expenditures into the various financing scheme categories. Since OTC drugs are not necessarily financed only by households, information on the reimbursement of OTC drugs by the various financing schemes should be identified. In the case of complex reimbursement arrangements for specific OTC drugs with facultative prescription status (e.g. in France where the social insurance reimburses some OTC drugs) the regulations can help data compilers build a complete methodology to estimate the expenditures on OTC drugs in the country.

18. Two different types of illegal sales of pharmaceuticals should be included in the estimates of OTC drugs according to the SHA 2011 Manual. The first refers to the domestic purchase without a valid

---

<sup>1</sup> There are legal requirements for a valid prescription detailing who is authorised to issue a prescription and in what circumstances.

prescription of those drugs for which the law requires a prescription. The second concerns the import of drugs that are not authorised for sale in the territory of the reporting country but that have been legally purchased abroad (e.g. abortion pills, Temazepam, Methamphetamine).

### **Data sources used to measure OTC drugs expenditures**

19. The majority of countries usually combine various data sources to estimate expenditure on OTC and its breakdown by financing agents/schemes and providers. The most common practice is to identify a primary source, either from the demand or supply side, which allows an estimate of the total expenditure on OTC then use one or more additional data sources to break down the aggregate into its sub-components.

20. Some countries privilege a demand-side approach relying primarily on the Household Budget Surveys or National Accounts Households consumption while others opt for supply-side data as their main source, either employing retail sales statistics or specific statistics compiled by specialised companies.

21. This section describes some of the characteristics and practical issues around the use of household budget surveys, data on sales of retailers (providers in the SHA framework), administrative data from national administrative bodies or social (insurance) schemes and, finally, specific pharmaceutical-based surveys.

### ***Household Budget Surveys (HBS)***

22. Household Budget Surveys (HBS) are a frequent data source used to estimate expenditure on OTC drugs (e.g. in Estonia, Iceland, Korea, Poland and Slovenia). The HBS usually contains detailed information on the consumption of health products including, for instance, pharmaceutical products and therapeutic appliances and equipment. HBS are usually easily accessible, available at regular intervals and their methodology is generally well documented. Moreover, questions are organised so to allow the compilation of household consumption statistics according to the COICOP classification which, under certain circumstances, can be directly related to the SHA categories. In some cases, this can go even further - for example, the HBS in Korea includes a specific question on OTC. Also, Household Budget Surveys are based on consumer prices and thus final expenditures by households, with no need for taxes or other price adjustments. Finally, the HBS includes goods and services purchased by the resident households either in the country or abroad. Again, no further adjustment is required to include imports and exclude exports.

23. On the downside, however, the use of HBS may be challenging for a number of reasons; the list of products may not be detailed enough, the estimates can be influenced by the subjective nature of the respondents, no information is available on the provider and, by its nature it only relates to private household expenditures. Since the HBS is not primarily designed to explicitly measure expenditures of OTC drugs it may not differentiate between prescribed and non-prescribed drugs and therefore blends the private expenditures on drugs into one group. The household members also do not precisely remember the exact expenditures on individual items which can cause some inaccuracies in the estimates (non-sampling errors). This may vary across countries and cultures as long as the health problems are sensitive topics for some people. The HBS do not usually include information on the type of vendor where the consumption item was purchased. Only the total cost of the item is recorded, or in some cases only the quantity. This can hinder the disaggregation of OTC drugs expenditures by provider in the SHA framework. The same problem exists for the financing scheme axis since the HBS covers only private expenditures.

### ***Final consumption expenditure of households by consumption purpose***

24. Final consumption expenditure of households elaborated within the national accounts and broken down by consumption purpose (i.e. COICOP categories) is another possible source of information

sometimes used to compile OTC in SHA (e.g. in Sweden and Spain). As in the case for HBS, the classification adopted as the international standard identifies only an aggregate category for all pharmaceutical products consumed (Class: 06.1.1 Pharmaceutical products). No further distinction is included. In some countries, however, a more detailed national classification may have been developed by adding one or two extra levels to the international hierarchy to address specific needs. In Sweden, for instance, a specific sub-class for OTC drugs has been introduced (sub-class 06.1.1.2) which provides the basic elements for the estimation of OTC in SHA categories.

### ***Providers' sales***

25. Data on provider's sales are another important source of information often used to estimate expenditure on OTC drug in SHA. Specific surveys on OTC sales are available in a few countries (e.g. Australia, Canada, France, Germany and Sweden). Such surveys may be carried out by private companies as well as by national authorities (e.g. Sweden and Finland). In addition, information on sales of pharmaceutical products may also be available through official statistics on retail sales for the whole economy. However, such surveys tend to use aggregate categories (such as ISIC or CPC categories) so that the distinction between prescribed and over the counter drugs is not possible.

26. In Canada, the private company Nielsen carries out a specific survey on sales of OTC drugs in drugstores, convenience stores, supermarkets and petrol stations to extend the coverage beyond traditional retailers of OTC drugs (e.g. pharmacies). The Swedish state-owned company Apotekens Service AB is in charge of a similar survey collecting information on sales of OTC by any authorised provider. Such a survey is the primary source used to compile the National Accounts' Final consumption expenditure of households mentioned above.

27. The downside of obtaining data from private companies in this field might be related to the market sensitivities and value attached to such data reflected in the charges for their use.

### ***New challenges for the data by provider***

28. The OTC market has developed rapidly over recent decades. New distribution channels such as internet or mail-order have been authorised in a number of countries. In addition, the OTC market has been opened to retailers beyond the traditional pharmacy (e.g. supermarkets).

29. The purchase of OTC drugs through internet or mail-order does not present specific difficulties for SHA compilers as long as it represents just an additional distribution channel for established "traditional" providers of pharmaceuticals. Particular attention should be paid, however, to those providers which are resident abroad since the purchase should be recorded under "Rest of the world" HP.9 in the importing country and should also be excluded from the SHA estimates of the exporting countries.

30. More complicated is the case of the new providers authorised to sell OTC such as grocers or supermarkets. The potential increase in the number of vendors and the consequent fragmentation of the market may cause difficulties requiring the development of a new sampling strategy to accurately estimate the expenditure on OTC.

### ***Administrative data on pharmaceutical market***

31. Administrative data from national pharmaceutical regulatory bodies or from social (insurance) schemes may be used as an additional data source to supplement the primary data sources on the share of prescribed and non-prescribed drugs sold, and on public reimbursement of pharmaceuticals.

32. Several countries (e.g. Estonia, Finland, Iceland and Slovenia) use data from social (insurance) scheme reimbursements to estimate total expenditures on pharmaceuticals or on specific OTC drugs (OTX, semi-ethics). Specific codes attached to OTC drugs are used in the administrative data (for example in Estonia or in Turkey) but this tends to be exceptional. Most countries use this source of information to estimate expenditures on prescribed medicines as a secondary source in OTC drug estimates (e.g. Spain).

### **Mapping of OTC drugs to the SHA framework**

33. This section provides information on how to map national data sources on OTC to the relevant categories of the System of Health Accounts. Mapping the data represents the third step of the general approach proposed in this report.

34. To facilitate the mapping exercise, this section first reviews the definition of OTC drugs proposed by SHA 2011 with some further clarifications. The section also spells out to what extent the new definition differs from that included in SHA 1.0. Some countries' experiences in mapping original data sources to SHA are finally presented.

#### ***The SHA 2011 definition of OTC***

35. SHA 2011 defines OTC drugs as “all pharmaceuticals, including branded and generic pharmaceutical products which may or may not be available without prescription but have been purchased independently” adding that “Inclusions on this category should be linked to the health purpose”.

36. Two aspects of the new definition are worth clarifying: “the independent purchase of a drug” and “the health purpose”. “Independent purchase” refers to self-prescription, that is, an independent decision to consume (purchase) the drug without a written prescription (“advice”) from a healthcare professional. The fact that the very same drug could also be prescribed becomes irrelevant for SHA 2011 (“which may or may not be available without prescription“) while the ultimate goal, the health purpose, become the most relevant criteria to include a product in the SHA boundaries (functional approach).

37. The dispensing and purchase of a drug upon presentation of a valid prescription issued by a qualified person is relevant to differentiate between the categories of “prescribed medicines (HC.5.1.1)” and “OTC drugs (HC.5.1.2)”. In practice, all products defined as drugs by national legislation and that have been purchased without a prescription should be classified as OTC.

38. Finally, the mode of financing (scheme) – and, in particular, the status of reimbursement – is not a criterion for the identification of OTC drug expenditure, nor is the provider – that is, from where the drug has been purchased.

#### ***Differences between SHA 2011 and SHA 1.0 definitions***

39. SHA 2011 has refined the OTC definition opting for a pure functional approach instead of the cross-dimensional approach used in SHA 1.0. In fact, SHA 1.0 defines OTC drugs also using the financing categories so that a drug could qualify as OTC only if funded as part of “private households' pharmaceutical expenditure”. SHA 2011 has abandoned any reference to the financing scheme allowing therefore any scheme in theory to finance OTC. In this way, countries where OTC can be reimbursed or purchased by schemes other than households can be accurately reported.

40. Moreover, SHA 1.0 also considers those drugs that, although prescribed, were not reimbursed as OTC (“*Over-the-counter (OTC) may be included in physician prescriptions, though not reimbursed*”: SHA 1.0 page 120). SHA 2011 takes a different route focusing exclusively on the self-medication criterion to define OTC and not subject to the financing regime. Therefore, drugs included in a physician prescription

are always considered as prescribed regardless of their reimbursement status. For the same reason, SHA 2011 includes within OTC the purchase of drugs that, although requiring a prescription, have been illegally purchased without it. It states that “...*While such trade may be undesirable or illegal, if it meets the criteria of the health care boundaries then it should in principle be recorded in the accounts in the same way as legal actions.*” SHA 1.0, on the other hand, excludes illegal or non-certified health interventions (SHA1.0 paragraph 5.15) from its boundaries. Also, SHA 2011 includes in OTC those drugs that, although not tradable (licensed) in the reporting countries have been purchased abroad (imported).

41. Table 1 below provides a summary of the differences between SHA 1.0 and SHA 2011.

**Table 1 Classification of pharmaceuticals (HC.5.1) according to SHA 1.0 and SHA 2011**

Type of pharmaceutical	Purchased with prescription formulary	HC in SHA 1.0	HC in SHA 2011
Prescription medicines	Yes	5.1.1	5.1.1
Drugs with facultative prescription status	Yes	5.1.1 if reimbursed 5.1.2 otherwise	5.1.1
	No	Not clear	5.1.2
Drugs without prescription requirements (over-the-counter)	No	5.1.2	5.1.2
Drugs purchased illegally in the country of residence	No	Not included	5.1.2
Drugs purchased from abroad	Yes	5.1.1	5.1.1
	No	Not clear	5.1.2

***Drugs with facultative prescription status***

42. Drugs with facultative prescription status can cause some difficulties as information on whether they have been purchased with or without a prescription may not be available. Three groups of products are of particular note: the so called “Lifestyle drugs”, the OTX drugs and “semi-ethics drugs.

- The term “Lifestyle drugs” identifies those drugs aiming at improving the quality of life by treating non-life threatening and non-painful conditions such as baldness, impotence, wrinkles, or acne.
- Another group of drugs are OTX drugs. This is a group of drugs which can be purchased only on the presentation of a prescription formulary but the social (insurance) scheme does not reimburse it. As long as these drugs are purchase with a prescription they should be classified under prescription drugs.
- The last group of drugs are “semi-ethics” that include OTC drugs purchased without a prescription formulary which are reimbursed by social (insurance) scheme. Again these drugs should be classified under the OTC drugs. A case study illustrating the classification of drugs with facultative prescription status according to the SHA 2011 Manual is provided in the Annex.

43. The classification of Traditional, Complementary and Alternative Medicines (TCAM) falls under drugs with facultative prescription status. According to the SHA 2011 Manual they should be included in the pharmaceuticals if they fulfil the healthcare boundary.

#### *Country experience in mapping original data sources to the SHA categories*

44. The information gathered from data sources is mapped to the relevant SHA categories. In some cases the task is quite straightforward since a one-to-one correspondence can be established between the original data source and the SHA aggregate. More frequently, however, the most detailed categories of the original data source can be linked to two or more SHA categories. In such cases a method of disaggregation would be required (see Section 6). Finally, there also exist cases where the original data source can be associated to one or more sub-components of OTC, but only for a subset of the providers or only covering a part of the financing breakdown, resulting in some gaps remaining. For example, available information may only include OTC drugs sold in pharmacies, therefore leaving out those sold by other retailers (e.g. supermarkets). Such a case would require the use of some estimation technique or assumptions in order to fill the gaps.

45. A one to one correspondence to the SHA categories of expenditure on OTC (regardless of the provider of financing breakdown) is achieved in Sweden, Korea, Canada and Estonia. In Sweden and Korea the information on the consumption of pharmaceutical products (COICOP 06.1.1) is obtained from either National Accounts Households' final consumption estimates (Sweden) or Households' Budget Survey (Korea) and can be matched to the SHA expenditure on OTC. The specific OTC category (COICOP 06.1.1.2) estimated in the Swedish Households' consumption is in turn sourced from state own company Apotekens Service AB (ASAB) in charge of compilation of drug market statistics. In Korea, a specific question on OTC drugs is included in the Household's Budget questionnaire. Pharmacy wholesale statistics by the State Agency of Medicines is used in Estonia to estimate the total expenditure on OTC. A specific estimation technique is then used to allocate the expenditure on OTC to the relevant financing schemes. Canada maps a special tabulation purchased from the Nielsen Company to SHA OTC. This tabulation provides information at product level (OTC are identified by the Food and Drugs Act) and at provider level. At product level, the information is available on quantities sold and overall value. By provider, it also includes online and mail-order sales. All OTC drugs expenditures are classified as out-of-pocket payments.

46. In the absence of a specific breakdown, countries using information classified according to COICOP (either the Households Budget Survey or the Households consumption expenditure estimates from National Accounts) can map the consumption of pharmaceutical products (COICOP 06.1.1) to the sum of the two SHA categories HC.5.1.1 and HC.5.1.2 only (e.g. in Spain) and then estimate the two categories by means of additional auxiliary information. The next section of this report analysis in more details the methodology countries use to separate the two components.

#### **Final adjustments**

47. The final step consists in combining all available information into a consistent estimate across all relevant categories of the provider and financing scheme classifications. Depending on the quality of the data and on the estimation method used, the final stage may not be required at all (e.g. Canada, Czech Republic, Finland, Ireland, Germany, Sweden, and Switzerland), be limited to minor adjustments to reconcile trivial statistical discrepancies in between the different data source used (Slovenia and Korea) or consist of a more complex method to estimate OTC if information on OTC are not readily available (for example in Estonia, Spain and USA).

48. An indirect estimation method may be required when the top down approach to estimate OTC (or one of its sub-components) is applied<sup>2</sup>. The use of the top down approach may be dictated by the absence of specific information on OTC. For example, the value of total expenditure on pharmaceutical may be known through the Households Survey Budget but no-detailed information is available on the breakdown between prescribed or purchased OTC drugs (e.g. Spain). The indirect method could also be used to disaggregate OTC into its sub components. There may be case where various schemes can finance the expenditure on OTC but the available information is limited to a subset of them. In Estonia, for instance, information on the government expenditure on OTC is known while the households out of pocket component can be estimated from the Households budget survey (the annual ratio of prescribed medicines turnover to total annual medicines turnover is used). Therefore the amount covered by corporation can be estimated by subtracting the former two components from total expenditure on OTC (which is available from the State Agency of Medicines).

49. Interpolation and extrapolation techniques may be required where detailed information on OTC and its subcomponents is available for benchmark years only. As benchmark estimates are usually produced at lower frequency than recurrent estimations (often bench marks occurs every five years), interpolation techniques may need to be applied for the periods in between benchmarks while extrapolations may be required for the years following the last available benchmark (e.g. USA).

50. Finally, extrapolation techniques may also be required when available data are not as updated as required. . In such circumstances preliminary estimates can be obtained by extrapolating the most recent information. Revisions would then be made once data become available (e.g. Australia)

## **Conclusion**

51. This paper describes a four-step general approach to assist countries better estimate expenditures on OTC drugs. By following these steps countries will build a country-specific methodology to provide more accurate estimates according to the SHA framework. The general approach of estimating expenditures OTC drugs should lead to improved international comparability of overall expenditures on health based on the methodology of the System of Health Accounts.

52. The proposed general approach guides data compilers through four basic steps from legislation assessment, data source identification, mapping to the SHA classification and an appropriate final methodology to arrive at estimates of expenditure on OTC drugs covering all relevant financing schemes and providers.

53. The paper lays out clear definitions of OTC drugs according to SHA 2011 pointing out differences to SHA 1.0. This will help to improve current estimates and facilitate the switch to SHA 2011.

54. National legislation on pharmaceuticals and prescription status should be analysed in individual countries. The key information is the inclusion of the purchase of the drug without a valid prescription into the category of OTC drug spending. The second pivotal condition is the inclusion of the drug into the health boundary. Supplementary information on the financing scheme or provider is important to allow the allocation of the expenditure according to the respective axes (by provider or financing scheme).

55. All data sources identified have pros and cons and the most advisable way forward is therefore a combination of several sources as is the case with most countries. Typically there is one principle source of

---

<sup>2</sup> A top down approach consists in disaggregating a variable into its sub components by applying a statistical algorithm. It differs from the bottom up approach in that the latter estimates the variable as aggregation of its sub components,

information which is combined with secondary data sources to achieve the closest correspondence with SHA. Administrative data from social (insurance) system reimbursement combined with household budget surveys is one of the most frequent solutions. Data from private companies focusing on pharmaceutical market is also a very common approach. It is also advisable to cross validate estimates with more data sources.

56. The country examples show a wide array of estimation methodologies which the data compilers have chosen in order to provide accurate estimates. These examples should offer mutual learning and exchange of experience. Countries are facing similar problem in the estimation process but country specific measures have to be selected in order to comply with national legislation and available data sources to achieve accordance with the SHA framework.