



CURRENT PRACTICES FOR THE PROCUREMENT OF MEDICAL DEVICES IN MOROCCAN HOSPITALS

-SURVEY AND RECOMMENDATIONS-

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PART 1 - PROCUREMENT PRACTICES FOR MEDICAL DEVICES IN MOROCCO

Introduction

Several international actions have been initiated in order to gain a better understanding of the environmental and occupational hazards linked to the use of chemical substances, even for those already known about for many years. Amongst these substances, particular attention is now being made to chemical substances classified as CMR (carcinogenic, mutagenic, and reprotoxic).

For many substances, the debate has been on going for many years, like for instance for phthalates, which are widely used as a plasticiser in the formulation of PVC (Polyvinyl chloride). This plastic material can often be found in medical devices. In the phthalate family, DEHP (Bis (2-ethylhexyl) phthalate) is the most common and is classified as a CMR in category 2 - toxic for reproduction.

We are carrying out this survey on procurement practices in Morocco to create awareness and ask practitioners to be cautious when using medical devices containing PVC plasticised with DEHP. Numerous initiatives to substitute this chemical substance already exist around the worlds, some of which may be applicable to the Moroccan situation.

However, not all medical devices represent the same risk for patients, and certain patients are more sensitive than others. Therefore, it is important to identify the medical devices which pose the highest risk and the populations most exposed in order to replace these progressively in Moroccan health institutions.

This report details the results of a survey about the procurement practices for medical devices in Morocco. This survey was carried out with the objective of collecting information around the level of knowledge, and the attitudes and behaviours of professionals using medical devices containing PVC plasticised with DEHP.

Further objectives were to discover possible alternative approaches, to gain a better understanding of the Moroccan regulatory framework and the level of involvement of suppliers, as well as to suggest potential improvements to speed up the implementation of these substitution alternatives in our institutions.

Medical devices market in Morocco

Morocco is a state located in North Africa. It is bordered by the Mediterranean Sea to the north, and the Atlantic Ocean to the west. It is mainly covered by huge desert areas (the Sahara) and mountains (Atlas). Morocco's climate is Mediterranean along the coast, semi-arid inland, and continental on the highest mountains. It has two long seasons: dry and hot from May to September, and colder and humid from October until April.

Morocco is divided into 12 administrative regions,¹ themselves divided in 44 provinces and 24 municipalities.

The general data profile of Morocco² is:

- Total population: 34,246,000
- Total area: 710,850 km²
- Population growth (%): 1.05
- Annual population growth rate between 2004 and 2014: 1.25%
- Life expectancy³ (in years): 75.8
- Total fertility rate: 2.19
- Crude birth rate (for a thousand inhabitants): 17.6
- Crude death rate (for a thousand inhabitants): 5.4
- Total health expenditures in % of GDP (2015)⁴: 5.3
- Growth in spending between 2001 and 2014: 52%

The funding sources for healthcare⁵ in Morocco are:

- Public funding through taxation revenue
- Direct spending by private households
- Medical insurance coverage: AMO and RAMED
- Employer contribution: employer contributions from AMO
- International cooperation: Aid in the form of donations and loans

The Moroccan healthcare system is composed of all the institutions, resources and actions organised in order to implement the key health objectives. This healthcare system is composed of: the public sector, the non-profit private sector, the for-profit sector and the informal traditional sector.⁶

¹ Decree No 2-15-40 of 1st jourmada I 1436 (20 February 2015) organising the number of regions, their names, their chief-towns, as well as the municipalities and provinces composing them.

² <http://www.hcp.ma>

³ Health in numbers 2015 (edition 2016) – <http://www.sante.gov.ma>

⁴ Direction for planning and Financial Resources, Moroccan Ministry of Health.

⁵ National health accounts - Report 2015 http://www.sante.gov.ma/Publications/Etudes_enquete/Documents/Comptes Nationaux de la Santé Rapport 2015.pdf

⁶ Framework law No 34-09 BO N° 5962 of 19 Chaabane 1432 (21-07-2011), related to the healthcare system and care provision.

Each sector is composed as follows:

- Public sector:
 - Care provision from the Ministry: network of primary healthcare institutions (RESSP), hospital network (RH), integrated network of medical emergency services (RISUM), network of medical and social institutions (REMS) and national institutes and laboratories
 - Healthcare of the Royal Armed Forces
 - Municipal and community healthcare offices of hygiene
- Non-profit private sector:
 - Hospitals and healthcare institutions of the national social security fund, insurance companies, O.C.P. and the National Bureau for Electricity and Drinking Water
 - Insurance company dental practices and analytical laboratories
 - Hospitals and healthcare centres of the Red Crescent
 - Hospitals and healthcare centres of the Ligues et Fondations
- For-profit private sector:
 - Private hospitals and clinics
 - Private practices
 - Analytical laboratories, opticians, prosthetics and pharmacies

Morocco's healthcare infrastructure is mainly composed of 143 hospitals, 400 private clinics and 20 oncology centres. It also has five operational university hospital centres⁷ (UHC) (Casablanca, Rabat, Fes, Marrakech and Oujda)⁸ and two due to be completed (in Agadir and Tangier).⁹

In 2017 the Moroccan medical device market was estimated to comprise of around 80,000 medical devices. The range of medical devices that are available on the market is extremely broad and its number high. Globalisation and freedom of world trade makes the dissemination of these products very easy and the risk related to quality defects very high.¹⁰

Between 2014 and 2017, sales volumes increased by more than 10% given the rise of the budget dedicated to healthcare. Almost 90% of medical devices are imported, mainly from Europe, and only 10% are manufactured locally. 85% of the demand comes from the public sector (Ministry of Health, military hospitals, CNSS, UHC) and 15% from the private sector.¹¹

Generally speaking, the market (by volume) is dominated by new equipment, especially in the public sector. The medical devices market turnover is estimated to be 2 billion dirhams.

⁷ Law 82.00 enacted by Dahir 1.01.206 of 10 Joumada II 1422 (30 August 2001)

⁸ http://www.sante.gov.ma/Pages/Org_sous-tutelle/CHU.aspx

⁹ Sector strategy 2012-2016 of the Moroccan Ministry of Health

¹⁰ National pharmaceutical policy <http://www.sante.gov.ma/Documents/2016/02/PPN-Fr-2015.pdf>

¹¹ <http://www.cfcim.org/wp-content/uploads/2015/12/Sante-maroc2014.pdf>

With about 250 registered agents and distributors, Morocco is positioning itself as a centre for re-distribution to the rest of Africa. Manufacturers sell medical devices to distributors who then ensure the sale to the end-users. However, some distributors are unspecialised and usually not considered experts on the field. Some manufacturers train distributors on service aspects and also directly organise training sessions for the end-users.

Results of the survey

The survey was carried out over a three-month period and had two phases: quantitative and qualitative. The first phase, quantitative, consisted of sending a questionnaire to 305 healthcare institutions in Morocco. The second phase, qualitative, included 35 semi-structured phone interviews to cover more qualitative aspects and adjust for less represented industries.

The answers to the questionnaire are as follows:

1. Profile of the respondents

a. Distribution by gender and age

The survey was carried out at random amongst a heterogeneous group. The participants were from a wide age group. The average age group was between 36 and 39 years, and more than half the participants were less than 37-year-old.

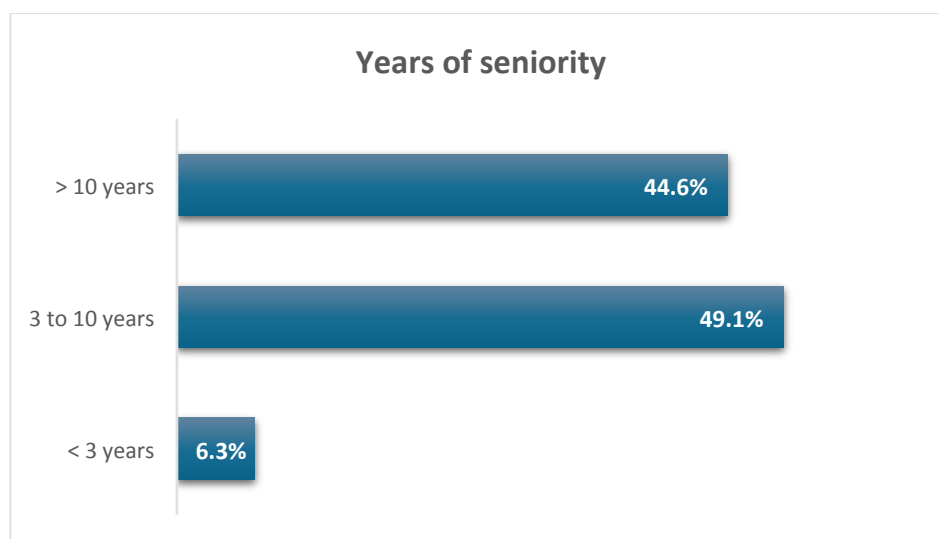
In addition, 57.1% of respondents were men and the other 42.9% were women.

Gender of the participants



b. Distribution by seniority level

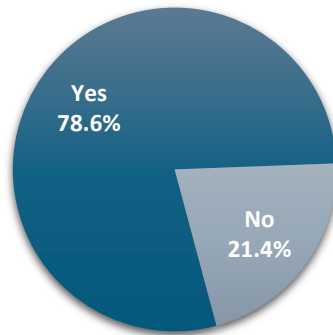
The number of years in active service (seniority) of the respondents in the institution ranged from 2 to 26 (average: 10.6). More than 9 out of 10 respondents had worked at their institution for over 4 years.



c. Distribution by responsibility level

The vast majority of the respondents occupy a function with high levels of responsibility (78.6%) of which 7.14% are directors. The respondents take part in the decision-making at different levels, notably, from the identification of the need until the post-purchase analysis.

Level of responsibility



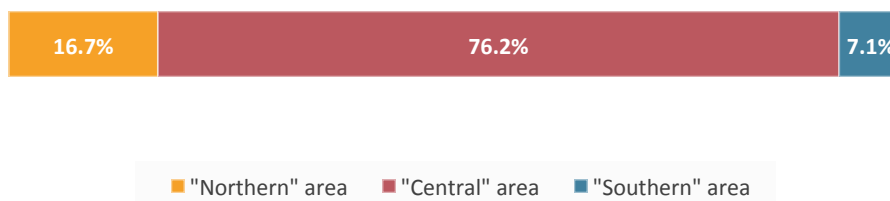
d. Distribution by geographical area

In order to establish a distribution by geographical area of the respondents, we have grouped postal codes according to the new 12 region territorial division of Morocco. For clarity, we have grouped the regions by geographical area according to the following classification:

- “Northern” area with 5 regions: Region 1- Tanger-Tetouan- Al Hoceima; Region 2- Oriental; Region 3- Fes-Meknes; Region 4- Rabat-Sale-Kenitra; Region 5- Beni Mellal-Khenifra
- “Central” area with 4 regions: Region 6- Casablanca-Settat; Region 7- Marrakech-Safi; Region 8- Drâa-Tafilalet; Region 9- Sous-Massa
- “Southern” area with 3 regions: Region 10- Guelmim-Oued Noun; Region 11- Laâyoune-Saguia al Hamra; Region 12- Ed Dakhla-Oued Ed-Dahab

More than three quarters of the participants come from the centre of the country; 16.7% from the North and 7.1% from the South.

Geographical distribution



e. Distribution by sector type

The target population for the survey was all healthcare institutions in Morocco:

- Care provision from the Ministry: the network of primary healthcare institutions (RESSP), hospital network (RH), integrated network of medical emergency services (RISUM), network of medical and social institutions (REMS)
- For-profit private hospitals and clinics
- Private practices

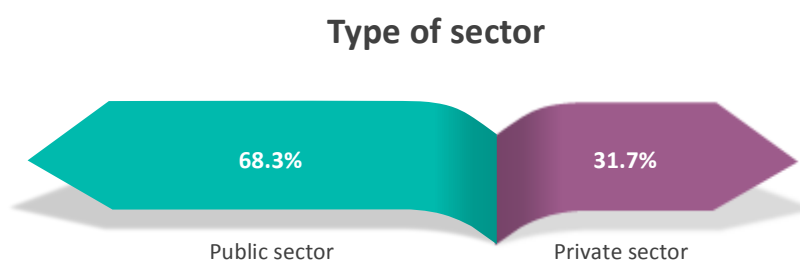
The following institutions were excluded from the survey:

- National Institutes and Laboratories Healthcare of the Royal Armed Forces, Municipal and community healthcare offices of hygiene
- Hospitals and healthcare institutions of the national social security fund, insurance companies, O.C.P. and National Bureau for Electricity and Drinking Water
- Insurance company dental practices and analytical laboratories
- Hospitals and healthcare centres of the Red Crescent, Ligues et Fondations
- Analytical laboratories, opticians, prosthetics and pharmacies

Within the framework of this survey, we have divided the healthcare provision in Morocco into two main sectors:

- Public, with healthcare provision from the Ministry of Health.
- Private, with for-profit private hospitals and clinics.

68.3% of participants come from the public sector and 31.7% from the for-profit private sector.



2. Level of knowledge and understanding of phthalates

Respondents' level of knowledge and understanding of phthalates was assessed regarding the presence and the exposure risks to hazardous chemical products in healthcare institutions.

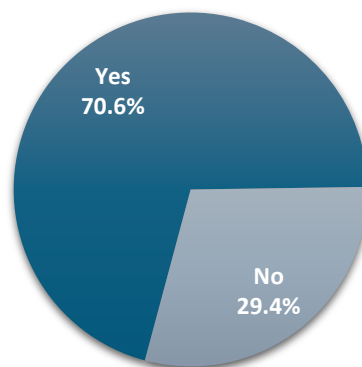
The level of understanding of chemical substances called “endocrine disruptors” - i.e. chemicals that modify the functioning of the hormonal system and/or cause harmful effects to the individuals exposed to them - was also been assessed.

In addition, the level of knowledge about CMR agents (agents with carcinogenic, mutagenic, and reprotoxic effects on the professionals who have been exposed to them) was also discussed.

a. Awareness about the presence of chemical products

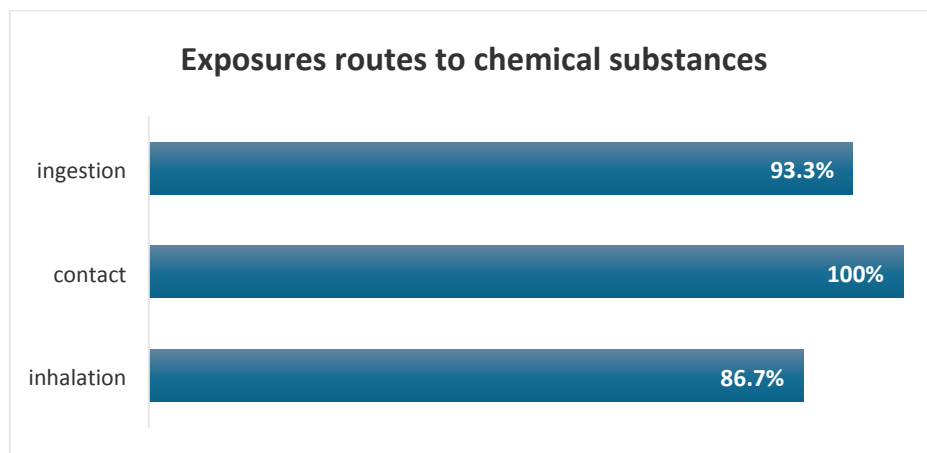
Most respondents (70.6%) consider the presence of hazardous chemical products as dangerous for the health and/or the environment in their institution.

Presence of chemical products



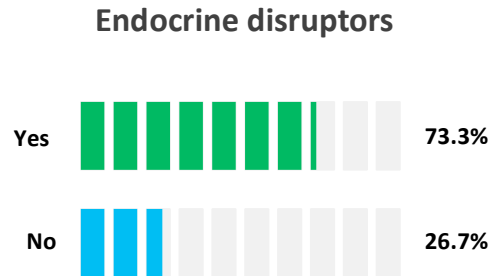
b. Identification of the exposure routes to chemical substances

More than 86% of respondents knew that people are exposed to chemical substances via three routes: inhalation, contact and ingestion.



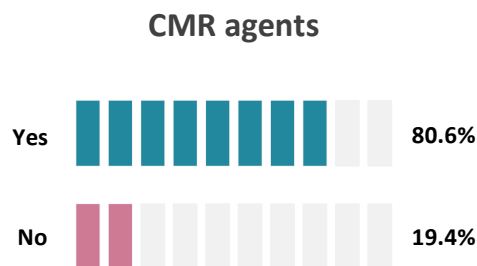
c. Understanding of the endocrine disruptors

More than 73% of respondents had heard of chemical substances likely to interact or interfere with the functioning of the endocrine system.



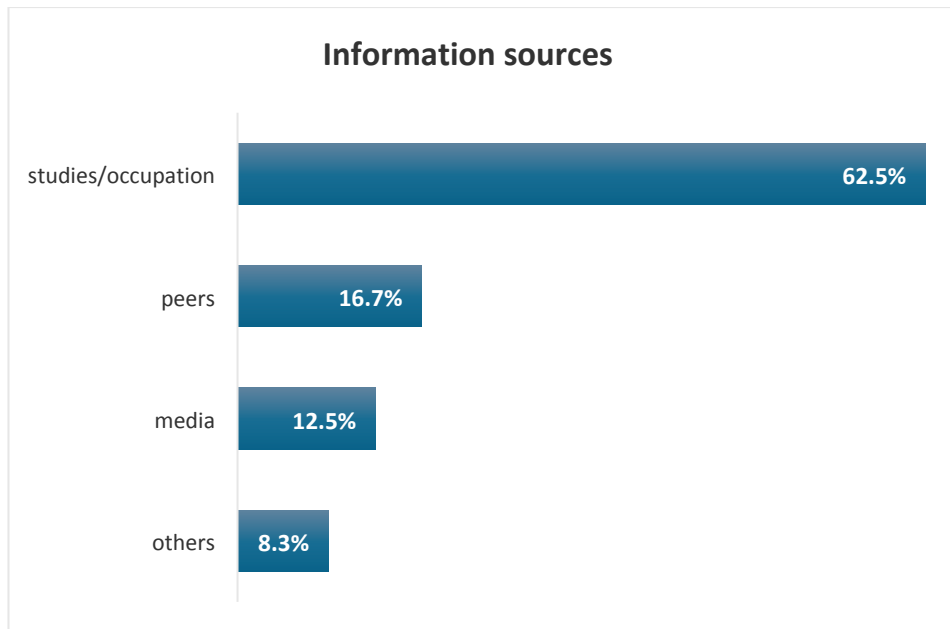
d. Knowledge of the CMR agents

The majority of respondents (80.6%) declared knowledge of chemical substances that have, in the medium to long term, carcinogenic, mutagenic or reprotoxic effects.



e. Information source

More than 60% of respondents declared having been informed about the phthalate plasticiser commonly used in PVC formulation through scientific studies. 16.7% were informed by their peers. 12.5% of respondents said they were well informed by the media (e.g. social networks, internet, television, literature, associations). The table below gives more details.

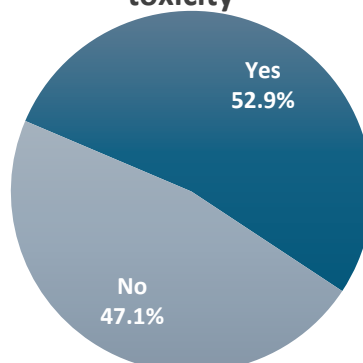


f. Knowledge about the phthalates and their toxicity

100% of respondents said that medical devices containing PVC are used in their institution and more than 50% of them were also aware of the toxicity of the phthalates used in those medical devices.

Respondents highlighted 40 medical devices containing PVC in their institution that can contain DEHP (di-2-ethylhexyl-phthalate), a derivative of phthalates. Amongst these medical devices: gloves, syringes, containers, medical consumables, catheters, tubes, blood bags, tracheotomy tubes, tubings, perfusion pumps, and dialysis catheters were identified.

Knowledge of phthalates' toxicity

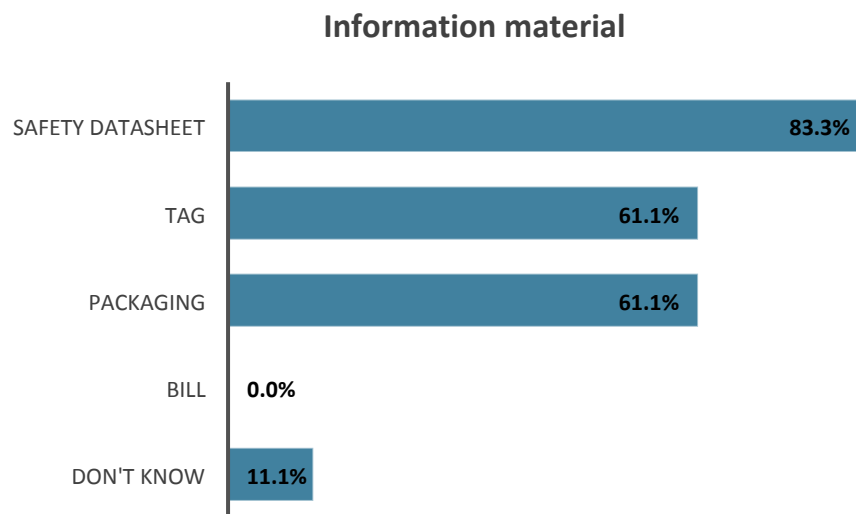


3. Level of knowledge of the tag and symbol

The level of knowledge of the tag and symbol for phthalates was also assessed. The results are indicated below.

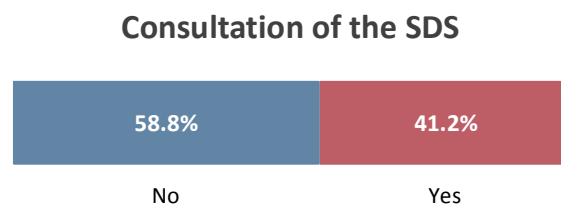
a. Knowledge of the information materials related to medical devices

More than half of the respondents mentioned where to find the information indicating the contents of the medical devices, namely the safety datasheet (SDS), the tag, and the packaging. Indeed, the tagging and the SDS provide essential information and their reading and understanding could prevent exposure to the risks linked to the use of medical devices.



b. Consultation of the safety datasheet

Almost 58% of respondents do not consult the safety datasheets of the medical devices. The SDS, which is essentially a summary of information for practical use, is a valuable source of information for the users and its main purpose is to assess the dangers and identify the risks that people are exposed to while using them.

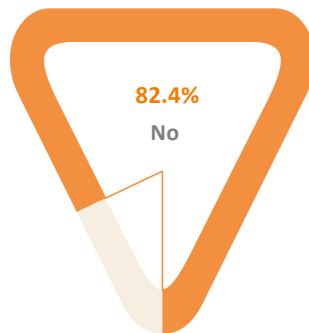


c. Knowledge of the DEHP pictograms

Most of the respondents (82.4%) do not know the pictograms (symbols) indicating the presence or absence of phthalates or DEHP.

The pictograms are graphics which immediately inform of the type of hazard that the medical device can pose. The pictograms have specific danger classes or categories.

DEHP pictogram

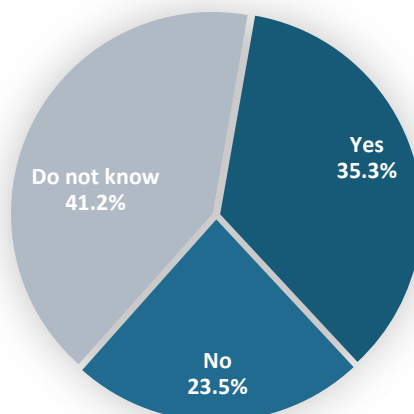


d. Reading of the tag on medical devices

Awareness of a contents tag on medical devices was also assessed. The medical devices' tag provides the following information: product identifier, first supplier identifier, pictograms, warning messages, danger notes, safety advice and additional information.

More than 41% of respondents did not know that the medical devices present in their institution are tagged. In addition, only 35.3% of respondents acknowledged having read the tag about the medical devices' content. 24% do not read the tags.

Reading of the MD tag



4. Regulatory aspects

In order to better understand and mitigate the risks related to the use of medical devices containing phthalates in healthcare institutions, several recommendations and regulations were implemented.

Certain substances, like phthalates, present in medical devices have harmful effects on human health and the environment. These effects can apply to the worker that manufactures them as well as to the users and end-user (patient).

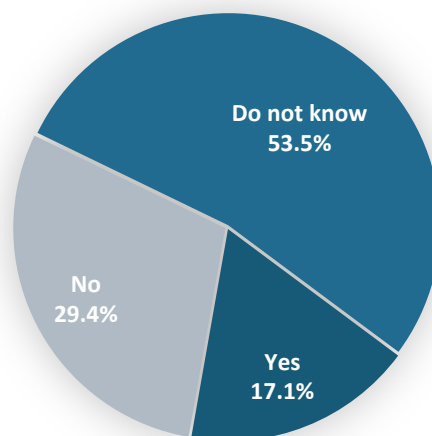
Generally speaking, the entire population is likely to be exposed to the release of these substances in the environment.

Awareness about the legal and regulatory provisions related to the presence of this substance in medical devices was assessed and the results are as follows:

a. Existence of professional recommendations

More than 53% of respondents do not know if there are professional recommendations on the use of medical devices in their institution, while 29.4% declare there are none.

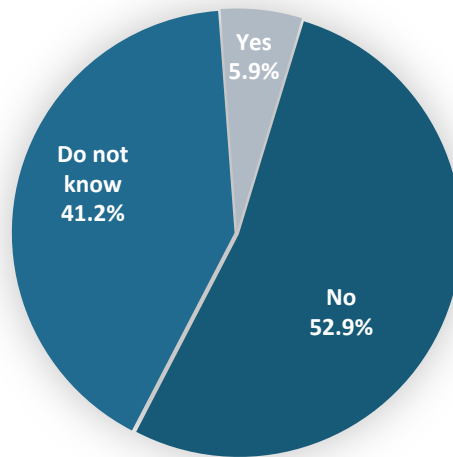
Existence of professional recommendations



b. Awareness of the regulations on phthalates

The vast majority of respondents (94.1%) do not know the regulation in force on phthalates present in medical devices.

Regulation on phthalates



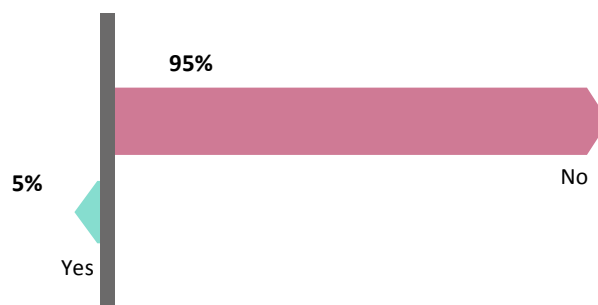
c. Awareness of the European regulation REACH

The European regulation No. 1907/2006 (REACH) (dated December 2006) provides a framework to the registration, assessment, and authorisation of chemical substances, as well as the applicable restrictions for these substances.

This regulation is based on the principle that it is up to the manufacturers, importers and downstream users to ensure that they fabricate, market, and use substances that have no harmful effects on human health or the environment. All of the provisions of this regulation are based on the precautionary principle.

In almost all cases (95%), respondents said they had not heard of the European regulation REACH.

REACH regulation



5. Alternative approach

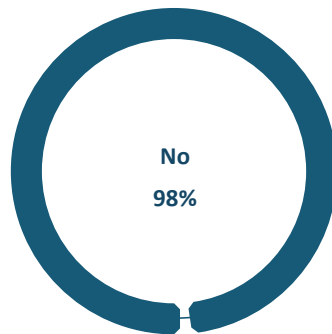
In order to give patients access to the highest quality, safest and most efficient medical devices, the regulation requires the substitution of the most hazardous chemical substances contained in the devices. It also highlights the importance of implementing the most documented information possible for the public on the risks linked to the use and/or the exposure to such substances.

In addition, the REACH regulation includes several provisions that aim to reduce the use of these substances and to withdraw the most concerning substances from the market while promoting alternative options.

a. Reduction of the use of MD containing PVC

98% of respondents declared that no particular provision was implemented to reduce the use of medical devices containing PVC.

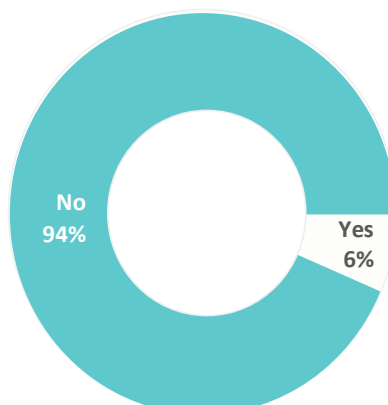
Substitution of MD containing PVC



b. Alternatives products awareness

More than 94% of the respondents have no knowledge of alternative products that do not contain hazardous chemical substances, notably DEHP.

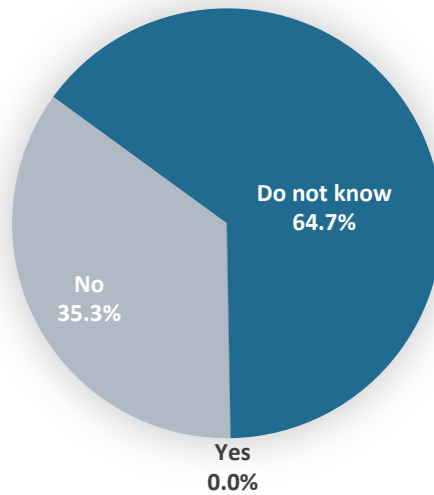
Alternative products awareness



c. Commitment to substitution policy

More than 35% of respondents confessed that their institution did not integrate any alternative products in their procurement policy. Furthermore, 64.7% were not aware of a substitution policy within their institution.

Substitution policy



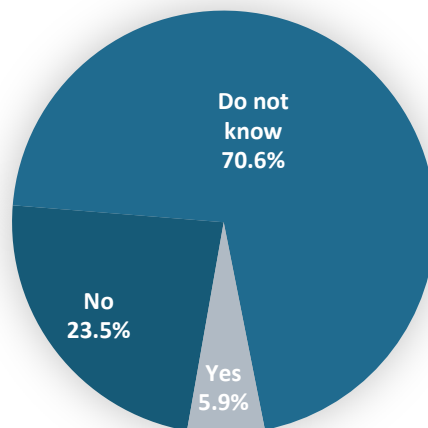
6. Integration of suppliers

Nowadays, healthcare institutions accept that they share the responsibility in terms of impact on the environment resulting from their suppliers' activities. They admit that they also have a real influence through the nature of their contracts with them. However, the introduction of environmental considerations in relation to suppliers, and more directly in the procurement process, must not be limited to the mere introduction of a contractual clause; it should rather be a mutual commitment to a progressive alternative approach of medical devices standards.

a. Suppliers' involvement

The majority of respondents (70.6%) do not know if their medical device suppliers are involved in a procurement approach of substituting alternative products. In addition, 23.5% of respondents seem to be sure that the suppliers were not involved in this substitution approach.

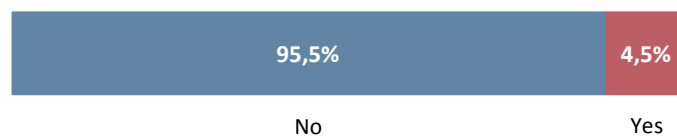
Suppliers' involvement



b. Suppliers' substitution approach

More than 95% of respondents do not know which medical device suppliers initiated a substitution approach to PVC plasticised with DEHP.

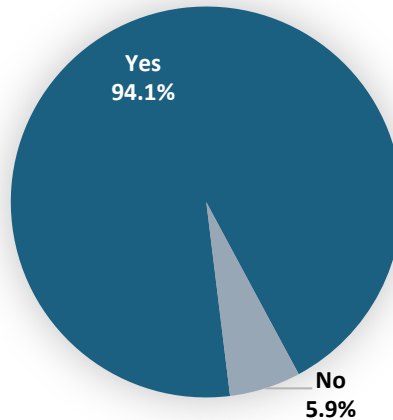
Suppliers' PVC substitution



c. Medical devices containing PVC inventory

More than 9 out of 10 respondents think that institutions should list the medical devices containing PVC plasticised with DEHP within their institution and test alternative medical devices.

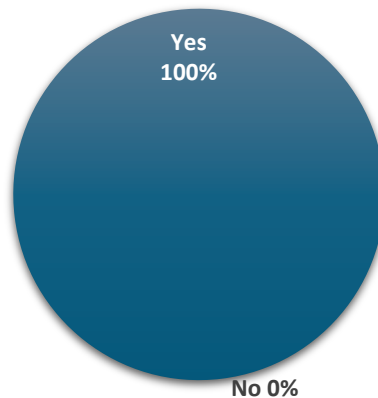
MD containing PVC inventory



d. Substitution of standard medical devices

All respondents wished to participate in procurement decisions for the substitution of standard medical devices with alternatives.

Substitution of standard MD



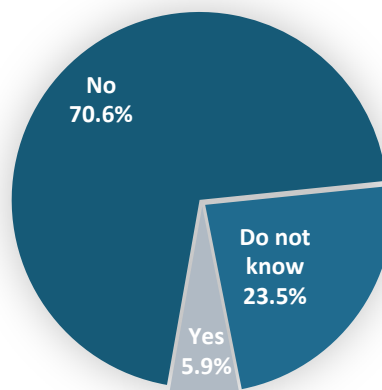
7. Training and sharing

Training and sharing refers to different learning activities likely to increase the knowledge and understanding of professionals, notably by increasing their capacity in terms of procurement practices. A regularly trained professional brings a lot of advantages to the institution, in the short and long term.

a. Awareness training

More than 70% of respondents did not benefit from awareness training about chemical substances in medical devices, notably the presence of DEHP. 23.5% of respondents do not know if training took place in their institution.

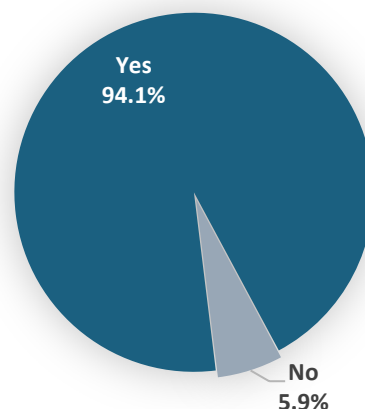
Awareness training



b. Training needs and advice

More than 9 out of 10 respondents wished to receive more information and practical advice about medical devices containing PVC plasticised with DEHP.

Information and advice



c. Exchange and information sharing

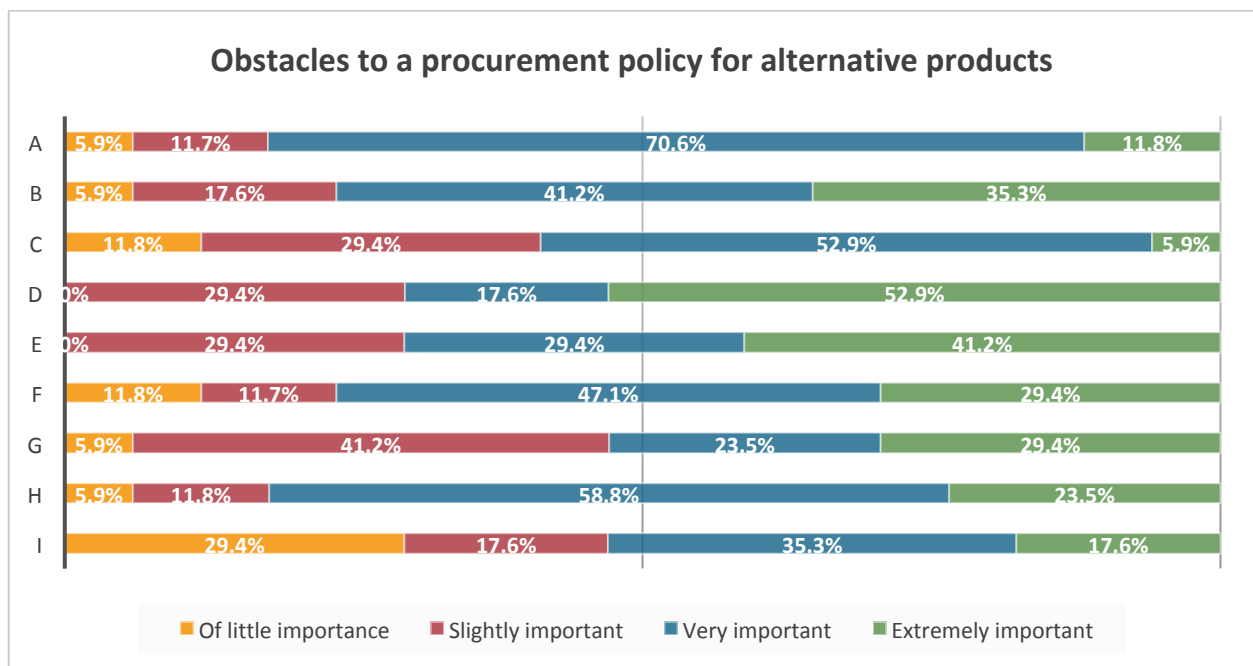
More than 56% of respondents confirmed their interest in participating in exchanges regarding the substitution of medical devices with alternatives within local, regional, national and European networks.

Interest in exchanging and sharing



d. Obstacles to the implementation of a substitution policy

The assessment of obstacles to the implementation of a procurement policy for alternative medical devices is summarised below.



- A- Lack of support and involvement in the hierarchy.
- B- Lack of political support (communal, regional, provincial, national).
- C- Lack of interest from those in charge of procurement.
- D- Lack of knowledge about the environment and the way to develop environmental criteria.
- E- Lack of training of the staff in charge of procurement.
- F- Lack of practical tools and information.
- G- Impression that more ecological products would be more expensive.
- H- Impression that more ecological products would not be easily available.
- I- Uncertainties around the legality of ecological public procurement.

All respondents identified the nine points mentioned as significant obstacles, which refrained their institution/companies from implementing procurement practices in favour of alternative products. Indeed, these nine obstacles were considered as very or extremely important (50%) by all the respondents.

The lack of support for a substitution approach was considered as very important for 70.6% and extremely important for 11.8%. A lack of knowledge about the environment and how to incorporate environmental criteria in orders was seen as extremely important for 52.9%.

The impression that more ecological products would not be easily available was also considered very important to 58.8%, and extremely important for 23.5%.

In addition, the impression that more ecological products would be more expensive was considered as very important for 23.5%, and extremely important for 29.4%. This issue was raised several times during phone interviews and meetings with healthcare professionals.

Procurement practices in Morocco

1. General information

Purchasing a medical device is an economic, technical and managerial action in which a product is acquired in return for financial compensation. Analysing the procurement function in a healthcare institution is not easy since it has a double purpose:

- Meeting a need. This includes the order decision, placement and management.
- Creating added value by integrating different aspects: quantity, quality, timeframe, safety, and controlled cost.

Procurement is not only one of the key functions for a healthcare institution to perform, but also one of the most complex because it requires logistical competence: mastering the diversity of medical devices and the mobilisation and synergy of the key players.

Medical devices:

Moroccan regulation defines a medical device as “any instrument, apparatus, appliance, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, together with the accessories and software required for its functioning, designed by the manufacturer to be used on the people for medical or surgical purposes. This includes any device that does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means”.¹²

According to the WHO, a medical device is “any medical device requiring activities of calibration, preventive and corrective service/maintenance, user training and deactivation - activities usually lying with biomedical engineers. The medical equipment is used with the specific aim of the diagnoses and treatment of disease or trauma or the rehabilitation of patients, and can be used alone or in combination with auxiliary equipment or consumables or other devices. The medical equipment does not include implantable, disposable or single use medical devices”.¹³

¹² Dahir n° 1-13-90 of 22 chaoual 1434 (30 August 2013) enacting Law No 84-12 related to medical devices.

¹³ Medical equipment service programme: general presentation – technical series of WHO on medical devices.

According to WHO estimates, there are currently about 10,000 categories of medical device, and between 90,000 and 1.5 million different products.

Procurement roles

Procurement personnel have different profiles depending on the variety, complexity, and technology of the hospital's activities.

In most cases, professionals take care of the purchases in their field: chemists, hospital engineers and technicians with various specialties, administrative executives and directors.

Procurement

Procurement procedures in healthcare institutions in Morocco are subject, like other public bodies (State, territorial collectives, public institutions), to public contract regulations. They can only be awarded if they meet the following constitutional principles: open access to public tender, competition between candidates, guarantee of competitors' rights, equal treatment of competitors, and transparency in the choice of the contractor.

These principles imply the respect of some basic rules: prior definition of the needs, following the notice publication rules, competition and selecting the most advantageous offer.

Consequently, the procurement for the public contracts in Morocco follows the principles and rules set by the regulation in force and takes place according to the terms and conditions foreseen by the decree on public contracts.¹⁴

The procurement methods in Morocco are:

- Tenders, that can be open or restricted
- Competitions
- Negotiated procedures
- Services against purchase orders

¹⁴ Decree No 2-12-349 of 20-03-2013 regarding the public contracts O.G. No 6140-25 of 04-04-2013.

2. Regulation regarding medical devices

Moroccan regulation on medical devices is aligned with international standards and the rules of the WHO that reinforce the requirements related to the compliance of the medical devices, their conception, production and launch. These medical devices are closely screened by health authorities and CE marking bodies (Notified Bodies).

In addition, the manufacturers of medical devices must be aware of the regulation to be able to keep their products in the market.

The base of the Moroccan regulation is composed of: Dahirs,¹⁵ laws, decrees, orders, circulars, and decisions coming from the ministers. Below is a non-exhaustive list of the regulatory base:

- Dahir of 12 rebia II 1341 (2 December 1922) regulating the importation, trade, detention and the use of venomous substances
- Law No 84-12 related to medical devices
- Dahir establishing law No 1-73-282 of 28 rebia II 1394 (21 May 1974) regarding the drug abuse control and prevention and modifying the dahir of 12 rebia II 1341 (2 December 1922)
- Law No 17 -04 on Drugs and Pharmaceuticals Code
- Law No 11-08 related to reagents used for in vitro diagnostics
- Circular regarding the list of medicines and medical devices essential for basic healthcare institutions in rural areas
- Circular regarding the authorisation procedure for the importation of medication and medical devices as donations
- Decree No 2-14-841 on the authorisation of the launch of medication for people
- Decree No 2-14-607 of 22 kaada 1435 (18 September 2014) for the application of law No 84-12 on medical devices
- Decree No 2-12-198 related to the bioequivalence of the generic medicines
- Decree No 2-12-149 of 3 jomada II 1433 (25 April 2012) for the application of law No 11-08 related to the reagents used for in vitro diagnostics
- Orders No 2853, 2854, 2855, 2856 on medical devices¹⁶

¹⁵ Act from His Majesty the King

¹⁶ <http://www.sante.gov.ma/Reglementation/Pages/REGLEMENTATION-APPLICABLE-AU-PRODUITS-DE-SANTE.aspx>

3. Overview of the procurement of medical devices without phthalates in Morocco

In recent years, awareness at the national level about the importance of replacing medical devices containing PVC plasticised with DEHP was reinforced by significant legal instruments.

The obligation to provide information on the composition of medical devices containing phthalates was mentioned in Annex 1 of the order of the minister of health (No. 2855-15 of 18 CHAOUAL 1436, 4 August 2015) on the registration and marketing of medical devices, and this Annex also fixed the conditions and procedure granting specific authorisation for medical devices not subject to being registered.¹⁷

In Morocco, several initiatives were carried out with the objective of substituting standard devices containing PVC plasticised with DEHP:

- Work of the research team in charge of the toxicological and pharmaceutical analysis, laboratory of pharmacology and toxicology of Rabat's faculty of medicine and pharmacy with the theme "Endocrine disruptors: what risk for the health?"¹⁸
- Work of the teams of Casablanca's laboratory of therapeutic Chemistry, Casablanca's laboratory of Pharmacognosy of the Faculty of Medicine and Pharmacy, and Oujda's laboratory of Pharmacology of the Faculty of Medicine and Pharmacy, with the theme "Medical devices with PVC: considerations on the DEHP and its risks for human health".¹⁹
- Work of the pharmacists of the UHC Mohammed VI of Marrakech,²⁰ who integrated the substitution of phthalates in medical devices for the preparation and the administration of chemotherapy treatments. Criteria supporting the purchase of medical devices without DEHP were integrated into the tenders related to the procurement of medicine and pharmacy products and accessories (MPPA) for the needs of the oncology-hematology centre at the UHC Mohammed VI de Marrakech.²¹

¹⁷ Order from the minister of health No 2855-15 of 18 CHAOUAL 1436 (4 August 2015)

¹⁸ Mina Ait El Cadi, Rachid El Jaoudi, Yassir Bouslimane, Abdelaziz Bouklouze, Yahia Cherrah. Endocrine disruptors: what risk for the health? Therapeutic medicine / Reproduction, gynecology and endocrinology medicine. 2011;13(2):102-109. doi:10.1684/mte.2011.0352

¹⁹ Sanae Derfoufi, Adnane Benmoussa, Amal Ait Haj Said, Zayneb Alami. Medical devices with PVC: Considerations on DEHP and its risks for human health. Moroccan Newspaper on Medical Sciences 2014; 19(4):7-11

²⁰ <http://www.chumarrakech.ma>

²¹ <http://www.marchespublics.gov.ma>

Recommendations

These recommendations have been formulated based on the results of the survey, taking into account the analysis of the overview of the medical device procurement practices. These should serve as a base for developing guidelines or good practices for healthcare institutions in Morocco.

The main recommendations are as follows:

Recommendation n° 1: Implement a substitution policy

Develop a procurement policy that meets the needs of the institution, while favouring the purchase of medical devices without phthalates. Such a policy should aim to gradually integrate a cost approach as well as criteria for sustainable development in tenders and choice of suppliers, in order to respect the imperatives in terms of quality and safety of the care provided.

Substitution can be done at various levels - from a simple purchase decision to a total phase-out of medical devices containing phthalates. However, substitution implies radical changes in the procurement system; some of these changes will be desired and predictable, others unpredictable and uncontrolled.

Furthermore, the implementation of a procurement policy requires the support and involvement of the entire hierarchy of the healthcare institution. Successful substitution programmes also require political support (community, regional, provincial, and national) to overcome the challenges of substitution, as well as the development of policies encouraging the implementation of devices without phthalates.

Recommendation n° 2: Develop and organise training

Implement a training and awareness programme for personnel involved in the purchase and use of medical devices in order to improve their knowledge of hazardous chemical substances such as DEHP as a derivative of phthalates (di-2-ethylhexyl-phthalate), the predominant plasticiser in medical devices containing PVC.

The following topics should be covered as a priority:

- Endocrine disruptors
- Agents having carcinogenic, mutagenic, and reprotoxic effects (CMR)
- Phthalates
- DEHP (di-2-ethylhexyl-phthalate) as a derivative of phthalates
- Alternatives to PVC plasticised with DEHP
- Procurement practices

Carry out information and awareness raising campaigns amongst different personnel about the tagging system for medical devices. In addition, these campaigns should have the objective of raising awareness about the symbols

indicating the presence of phthalates, their meaning, and the importance of safety datasheets (SDS).

It is also important to organise specific training (e.g. workshops, symposiums) on substitution for staff involved in procurement for healthcare institutions and who already have a basic scientific knowledge about phthalates.

Recommendation n° 3: Reinforce the application of the regulatory framework

Reinforce the application of the legal, regulatory and institutional frameworks which aim to limit the effects of the hazardous chemical substances present in medical devices, notably the DEHP as a derivative of phthalates.

Currently, the existing regulatory base encourages substitution. However, in reality, substitution faces many obstacles such as low adherence to regulation and legal gaps weakening existing frameworks. Many institutions are willing to proceed with substitution, but are often not very inclined to do so because of the lack of adapted institutional mechanisms or governing bodies ensuring the application of the regulatory base.

Recommendation n° 4: List the medical devices containing PVC plasticised with DEHP

List all medical devices containing PVC plasticised with DEHP in healthcare institutions in order to develop a substitution plan. To achieve this, it is essential that the healthcare institution exercises its authority to influence, examine and improve substitution so that the expected results are obtained progressively at minimum cost, and with very limited negative or unwanted consequences.

Recommendation n° 5: Work with suppliers of medical devices

Sensitise the suppliers of medical devices to the environmental aims of purchasing alternative products and involving them in the substitution approach. The reluctance of suppliers to change can constitute the first and biggest obstacle to substitution. Many believe that substitution requires substantial efforts to ensure the availability of alternative products and that it leads to increased costs.

Consequently, the success of substitution demands close collaboration between healthcare institutions and suppliers in terms of risk assessment of alternative products. Furthermore, there is little information available about substitutes and many possible substitutes have not yet been identified.

Recommendation n° 6: Publish a best practice guide

Publish a best practice guide for the procurement of medical devices, including recognised practices, decision-making support, and a clear and easy-to-use presentation of the current knowledge. This guide would be particularly useful for

suppliers and healthcare institutions, allowing professionals to share the main steps that need to be taken in terms of substitution that are specific to the health sector.

Recommendation n°7: Create a network to share experiences

Create a network of experts and advisers for the purchase of medical devices without phthalates. It is important to capitalise and share experiences in terms of substitution at the international level. Available data and successful experiences in terms of substitution should be available for interested parties who want to start integrating these into their own practice. This information should also be available to the wider healthcare community.

Conclusion

The results of this survey highlighted the strong awareness of professionals about the presence of hazardous chemical substances in medical devices, particularly phthalates. However, their knowledge about technical aspects such as the pictograms of DEHP and tagging is limited. The survey also underlined how difficult it is to implement an institutional strategy of substitution in the absence of political support, support from management, and without the supplier's involvement.

The information derived from this survey provides a base for the assessment of the theoretical knowledge, attitudes, behaviours and the professional practices in terms of procurement of medical devices in Morocco.

The analysis carried out during the survey leads to the following conclusions:

- Information and awareness raising campaigns tailored specifically for professionals must be encouraged, since they improve the level of knowledge and environmental protection. This training and awareness raising reduces the exposure to risks and helps the adoption of new products and techniques.
- There is a need for accompanying measures to, on the one hand, adhere to existing regulations, and, on the other, to fill the legal gaps and loopholes in regulation. The adoption of a stricter legislation should restrict the use of medical devices containing PVC plasticised with DEHP.
- It is important to create a list of the medical devices containing PVC to assess the potential for substitution.
- The suppliers of medical devices are the key partners in successful substitution.
- The implementation of a substitution policy within the healthcare institutions is an important step to chart a roadmap.
- A best practice guide would allow professionals to share the key steps that need to be taken to adopt a substitution policy.
- A network of professionals to share information and capitalise on existing experiences needs to be created.

The results of this survey invite us to implement strategies, programmes, and tools to reduce the risks of exposure to medical devices containing phthalates.

PART 2 - BEST PRACTICE AND REGULATORY EXPERTISE FROM EUROPE

Regulatory framework for medical devices in Europe

In the European Union (EU), a medical device is defined any instrument, apparatus, software, material, or other product intended to be used for medical purposes such as diagnostics, prevention, treatment, or compensation for an injury or disability, among others.²² This definition comprises both simple and disposable products such as syringes or gloves, and complex medical devices e.g. defibrillators or surgical machines (Figure 1).²³ In addition, in vitro diagnostic medical devices can be distinguished as those that are used to perform tests on samples (e.g. HIV blood tests, pregnancy tests, and blood sugar monitoring devices). Taking a holistic view, there are over 500,000 types of medical devices and in vitro diagnostic medical appliances on the market across the EU.²⁴

High risk ↑ ↓ Low risk	Medical devices		In vitro diagnostic medical devices	
	Class	Examples	Class	Examples
Notified Body approval	Class III	Pacemakers, Heart valves, Implanted cerebral simulators	Class D	Hepatitis B blood-donor screening, HIV blood diagnostic test, ABO blood grouping
	Class IIb	Condoms, Lung ventilators, Bone fixation plate	Class C	Blood glucose self-testing, PSA screening, HLA typing
	Class IIa	Dental fillings, Surgical clamps, Tracheotomy tubes	Class B	Pregnancy self-testing, Urine strip tests, Cholesterol self-testing
Self-assessment	Class I	Wheelchairs, Stethoscopes, Spectacles	Class A	Clinical chemistry analysers, Specimen receptacles, Prepared selective cultural media

Figure 1: Classification of medical devices and in vitro diagnostic medical devices²³

²² Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Retrieved from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>

²³ MHRA (2017). An Introductory Guide to the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR). Medicines and Healthcare Products Regulatory Agency. Retrieved from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance_Print_13.pdf

²⁴ ec.europa.eu (2017). New EU Rules on Medical Devices to Enhance Patient Safety and Modernise Public Health. Published on 5 April 2017. Retrieved from: http://ec.europa.eu/growth/content/new-eu-rules-medical-devices-enhance-patient-safety-and-modernise-public-health-0_en

1. Background

The existing regulatory framework for medical devices originated in the 1990 and is rooted in the three major pieces of legislation:

- Council Directives 90/385/EEC on Active Implantable Medical Devices (AIMDD)
- Council Directive 93/42/EEC on Medical Devices (MDD)
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD)

Due to some issues surrounding the interpretation of the rules and associated incidents of malfunctions of medical devices, as well as advances in technology since their introduction, the Directives inevitably needed revising. The European Commission presented two proposals concerning medical and in vitro diagnostic devices in 2012. Followed by expert consultations, a general agreement on the approach to the medical devices package among Member States was reached in 2015.²⁴ Five years after the initial proposal, in 2017, the European Council adopted two new Regulations on medical devices that entered into force on 25 May 2017 replacing existing legislation:

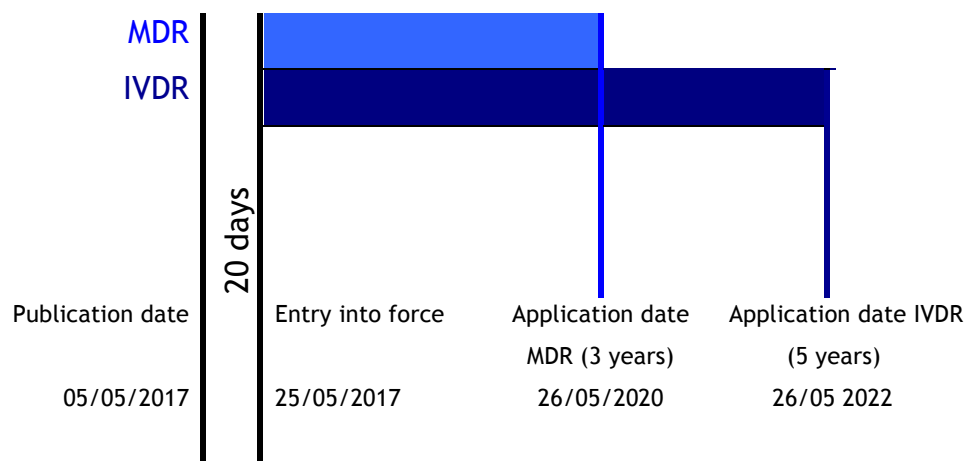
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR)
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR)

The new legislation was implemented with the objective of ensuring a high level of health and safety protection for EU citizens using the devices, enabling free and fair trade of such products throughout the EU, as well as aligning EU legislation with technological and scientific progress of recent decades.²⁵

²⁵ ec.europa.eu (2017). Medical Devices - Regulatory Framework. Retrieved from: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

2. Main provisions of the new legislation

The new Regulations for medical devices will only apply after a transitional period from their entry into force: three years for the MDR and five years for the IVDR (Graph 1).²⁶



Graph 1: Transitional period for MDR and IVDR²⁶

Based on the new rules, manufacturers of medical devices and in vitro diagnostic medical devices will be subject to stricter rules such as mandatory consultations with a pool of experts before introducing high-risk devices to the market or more controlled clinical trials of certain devices. Furthermore, in vitro diagnostic medical devices will be classified under a new system for risk classification according to international guidelines. In addition, new categories of medical devices (aesthetic products) that have not been regulated previously will be also included in the definition of medical devices.²⁴

The new legislation will also strengthen the role of national oversight bodies (Competent Authorities). A Competent Authority represents an institution that has been given authority in a specific policy area. For the MDR and IVDR, the Competent Authorities will usually be national Ministries of Health or other specialised agencies. They will be responsible for nominating Notified Bodies - organisations determining whether a device follows applicable requirements before being placed on the market. These Notified Bodies will be obliged to closely collaborate with Competent Authorities in a transparent manner.²⁷

²⁶ Bruyndonckx, A., & Mignolet O. (2017). The EU Medical Devices Regulations - Impact on Distributors [Presentation]. beMedTech 9 May 2017, Groot-Bijgaarden, Belgium. Retrieved from: https://www.bemedtech.be/wp-content/themes/twentyeleven-child/pdf/events/12052017_1494571948_fr.pdf

²⁷ HCWH (2017). Medical Devices Regulation - An Engine for Substitution? Factsheet. Retrieved from: https://noharm-europe.org/sites/default/files/documents-files/5257/HCWH_Europe_MDR_Factsheet-Dec_2017_FINAL_WEB.pdf

Best practice case studies

1. Vienna Hospital Association

The Vienna Hospital Association (KAV) represents 31 institutions including hospitals, geriatric centres, nursing homes, and training facilities. With over 30,000 employees, KAV annually provides healthcare services for 395,000 in-patients and 3.2 million out-patients. KAV's facilities have the capacity of 8,217 acute care beds and 3,082 geriatric beds.²⁸

PVC-free neonatal intensive care units

In order to protect the most vulnerable from hazardous chemicals, efforts to limit the use of medical devices containing PVC in neonatal intensive care units (NICU) started in the 1990s - the Glanzing Children's Hospital committed to gradually eliminate such devices and have been tracking the process of their substitution in 2001.²⁹

As a result of these wide-ranging activities, special audits were conducted to quantify the amount of PVC waste that the hospital produced (14.6% of the total weight of examined devices and 0.37% of the entire medical ward waste). Purchasing PVC-containing devices were prohibited when PVC-free alternatives exist.³⁰ In June 2003, the NICU became the first in the world to declare its commitment to phasing out PVC completely.³¹

At present, the vast majority of invasive medical devices are free from PVC including pump syringes, tuberculin syringes, pricking needles, connection tubes, suction tubes, feeding tubes, mixing valves, spinal cannulas, ventricular drains, infusion bags, catheters, tracheostomy equipment, blood filters, and bottle teats. Medical devices containing PVC such as certain types of catheters and respiratory equipment (e.g. tracheal tubes, tracheostomy) are rarely used, and only intended for short-term use.³² At the hospital level there are also efforts to eliminate PVC in other areas including construction, when it is economically and technically justifiable.³³ As a result of this approach, the amount of PVC found in their medical waste has decreased from approximately 10% of total weight in 1992 to 0.6% in

²⁸ KAV and City of Vienna (2018). The Vienna Hospital Association (VHA). Presentation on the Association retrieved from its Department of Environment.

²⁹ Lischka, A., Mad, P., Nentwich, H., & Klausbruckner, B. (2011). Substituting Phthalates in Plastic Medical Devices: The Austrian Experience-PVC-Free Neonatal Intensive Care Unit of Children's Hospital Glanzing in Vienna. *Journal of Environmental Science and Engineering*, 5(9).

³⁰ HCWH Europe (2004). Preventing Harm from Phthalates, Avoiding PVC in Hospitals. Retrieved from: https://noharm.org/sites/default/files/lib/downloads/pvc/Preventing_Harm_From_Phthalates.pdf

³¹ HCWH Europe, VHA & City of Vienna (2003). Glanzing Clinic in Vienna Is First PVC-Free Paediatric Unit Worldwide. News release published on June 13, 2003. Retrieved from: https://noharm.org/sites/default/files/lib/downloads/pvc/Glanzing_First_PVC-Free.pdf

³² Children's Hospital - Kinderklinik Glanzing (2013). Children's Clinic Glanzing, the first PVC-free Neonatal Intensive Care Unit (NICU). Presentation by Professor Andreas Lischka. Retrieved from: https://noharm-uscanada.org/sites/default/files/documents-files/2663/2013-03-21_Lischka_Children%27s_Clinic_Glanzing_the_first_PVC-free_neonatal_intensive_care_unit_%28NICU%29.pdf

³³ Environmental protection at the Vienna Hospital Association: Retrieved from: <http://www.wienkav.at/kav/umweltschutz/ZeigeText.asp?ID=7061>

1999³⁴. More recently, this has been declining systematically down to 0.24% of total waste in 2010 (Table 1).³⁵

Year	Products containing PVC delivered to the NICU		Waste containing PVC (% of total waste Cat. I and III)
	Weight (kg)	Weight (% of total waste*)	
2001	343	14.6	0.47
2003	272	11.6	0.37
2007	264	11.2	0.36
2009	212	9.0	0.29
2010	178	7.6	0.24

*The total annual waste at NICU extrapolated out of the quantity of waste containers used per year was 2353 kg.

Table 1: Amount of PVC-containing devices delivered and generated waste at the NICU, Glanzing Paediatric Hospital (2001-2010)³⁵

Sustainable procurement of disinfectants

The Vienna Hospital Association (KAV) also practices environmentally sustainable procurement for their disinfectants as part of the City of Vienna's sustainable procurement programme: *EcoBuy Vienna*. Established in 1998, the programme focuses on promoting climate protection and proposes ecological criteria when purchasing goods and services in all areas of city administration.³⁶

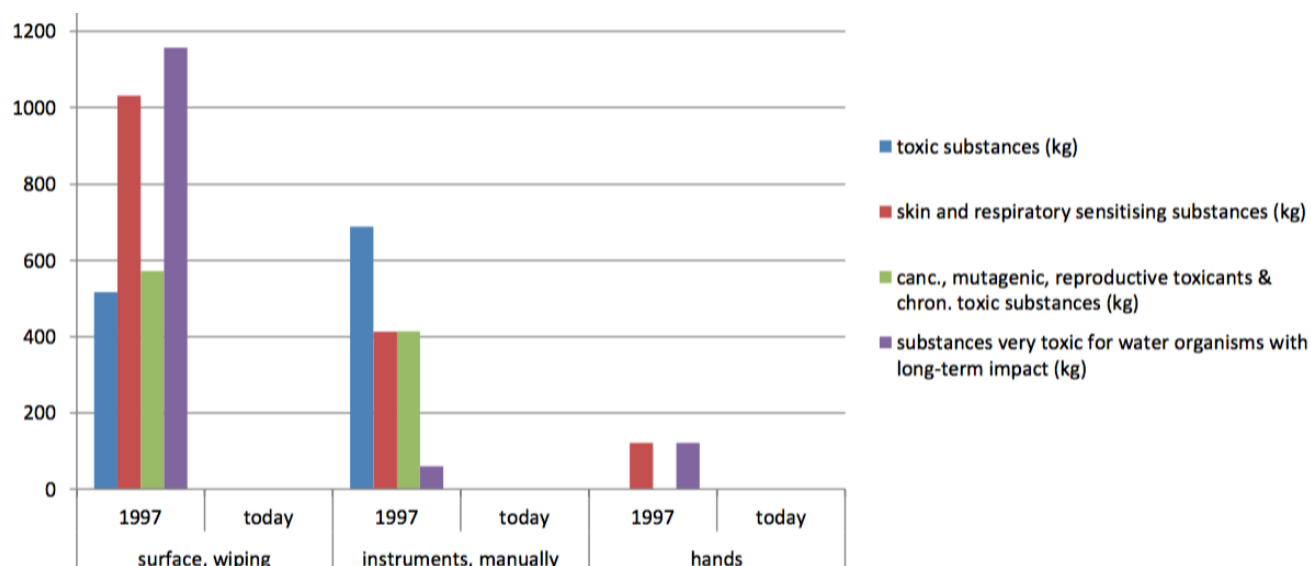
The Vienna Database for Disinfectants, *WIDES*³⁷, is a prominent feature of the programme. *WIDES* provides information and allows comparisons of performance indicators for various groups of disinfectants and is accessible to major city procurers and the general public. It is mandatory for the KAV's hospitals to use the database and (through a consultation with hygiene experts) performance profiles are created for all disinfectant groups relevant for their operations. Tender processes can be further conducted based on these performance profiles.

³⁴ HCWH Europe (2007). PVC/DEHP Phase-out Is Possible Anywhere in Europe: Model Hospitals Show How to Succeed. Factsheet. Retrieved from: https://noharm-europe.org/sites/default/files/documents-files/2675/PVC_DEHP_Phase-Out_Europe.pdf

³⁵ Lischka, A., Mad, P., Nentwich, H., & Klausbruckner, B. (2011). Substituting Phthalates in Plastic Medical Devices: The Austrian Experience-PVC-Free Neonatal Intensive Care Unit of Childrens Hospital Glanzing in Vienna. *Journal of Environmental Science and Engineering*, 5(9)

³⁶ City of Vienna. Ecological Criteria Catalogues and Impact Analysis. Retrieved from: <https://www.wien.gv.at/english/environment/protection/oekokauf/criteria-catalogues.html>

³⁷ The Vienna Database for Disinfectants - "WIDES". Available at: <http://www.wides.at>



Graph 2: Substitution potential for substances with especially hazardous properties by adhering to the WIDES recommendations at the Vienna Hospital Association³⁶

Through the *EcoBuy Vienna* programme, the Vienna Hospital Association (KAV) have made considerable ecological, economic, and social savings - the procurement volume of cleaning agents has dropped by 37% since the applying the *EcoBuy Vienna* programme, saving nearly €30,000 annually. Reducing pollutants in working environments (Graph 2) has also significantly contributed to improving the staff working experience.³⁶

The success of the PVC-free neonatal unit and sustainable procurement programmes implemented by the Vienna Hospital Association can be largely attributed to the wider local agenda of addressing environmental concerns, adding additional momentum and mobilising political interest.³⁸ The market power of this significant procurer, both for PVC-free medical devices and disinfectants, was essential in creating new cooperation and communication with potential manufacturers.³⁶

³⁸ OECD (2003). The Environmental Performance of Public Procurement: Issues of Policy Coherence. Organisation for Economic Cooperation and Development: Paris.

2. The PVC-free Blood Bag project

The PVC-free Blood Bag project was conducted between September 2011 and June 2017 and was supported by the EU's Life+ Environmental Programme. The objective of the project was to produce a set of blood bags that could successfully store red blood cells, meet the required specifications, and be completely PVC-free. No blood bags currently manufactured are free from PVC or phthalates (acting as plasticisers in medical devices). The secondary objective of the project was to expand demand for PVC-free alternatives through awareness-raising and disseminating knowledge through the network of European healthcare stakeholders.³⁹ The project included a partnership of four European companies (Melitek A/S, Wipak Oy, Primo Profile, and Haemotronic SpA), who worked together to create a PVC-free blood bag. Project partner Karolinska University Hospital was responsible for the evaluation of the final product whilst Jämtland County Council performed and monitored the testing phase.⁴⁰

Although the project started in 2011, it was initiated a few years earlier by a group of Swedish healthcare institutions. The pilot study conducted at that time distinguished areas for technical improvement, specifically issues associated with welding and sterility. This exercise was crucially important for identifying key obstacles to the introducing PVC-free blood bags to the market, (most of which still apply).

There is still no available technology to appropriately reflect the performance of PVC and DEHP when combined; consequently a high level of investment is required in order to introduce such a product to the market. The costs associated with introducing such technology would likely affect healthcare procurers, that is why demand for PVC-free alternatives remains relatively low. The entire supply chain needs to be engaged in the process of replacing traditional blood bags - which will be difficult to achieve due to the vested interests and lobbying of plastic manufacturers. A lack of awareness of the health hazards associated with PVC-containing devices in healthcare settings, combined with existing procurement contracts do not help support for substitution.

Encouragement from respective legislators would significantly help facilitate the transition, but there is no harmonised legal and institutional system that could accelerate it.⁴¹ A further complication of the PVC-free blood bag is its multifaceted supply chain, extended to several countries. The manufacturing process starts in Denmark where Melitek produces the compound, and then sent to two companies in Finland and Poland that manufacture its essential components (film and tubing, respectively). Haemotronic produces the bags in Italy whilst

³⁹ PVCfreeBloodBag (2017). Layman Report 2017. One Step Closer to a Safe Blood Bag: Public Healthcare and Plastic Makers Demonstrate How to Remove Barriers to PVC-free Blood Bags in the Spirit of REACH. Retrieved from: <http://www.pvcfreebloodbag.eu/wp-content/uploads/2015/02/Layman-report-PVCfreeBloodBag.pdf>

⁴⁰ Handout (2014). Would You Buy a New Type of Blood Bags? Retrieved from: http://www.pvcfreebloodbag.eu/wp-content/uploads/2015/02/Would_you_buy-3.pdf

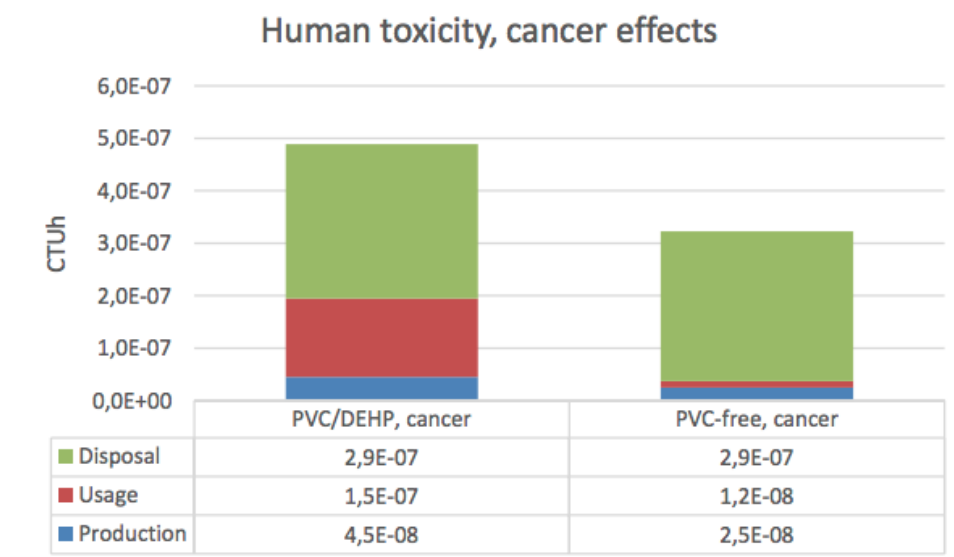
⁴¹ Jegrelius Institute for Applied Green Chemistry (2010). The Art of Buying What is Not Available on the Market. Blood Bags - a Pilot Case to Stimulate Ico-Innovation Within the Healthcare Sector. Final Report - Vinnova Project Reg. No. 2008-0381. Retrieved from: http://www.pvcfreebloodbag.eu/wp-content/uploads/2013/11/BloodBags_final_report_krcopy.pdf

external suppliers provide the remaining components. The bag is then ready to be tested by the Swedish partners (Karolinska University Hospital and Jämtland County Council).³⁹

The finished product was extensively tested for its storing properties and usability and underwent CE marketing pre-audits as well as a life cycle assessment.

At the same time, efforts were to raise awareness of the project and the demand for its final product continued through meetings and consultations with healthcare stakeholders and decision-makers. Various communication channels were used to promote the concept of the PVC-free blood bag e.g. website, video materials, brochures, and newsletters.

As a result, the project offered a PVC-free alternative to traditional blood bags, one that is safer for human health with due technical performance. As the impact assessment showed, human toxicity of PVC/DEHP sets was considerably higher in comparison to the proposed PVC-free set (Graph 3), mostly due to the fact of eliminating DEHP leakage during blood storage. The project proved that it is possible to reduce the risks of toxic effects on human health when using the PVC-free alternative and, at the same time, lower environmental risks related to production, usage, and incineration.⁴²



Graph 3: Human toxicity for PVC/DEHP and PVC-free blood bag sets (expressed in Comparative Toxic Units - CTUh)⁴²

⁴² Sjons, J & Wendin, M. (2017). PVCFreeBloodBag - Life-Cycle Assessment. Retrieved from: https://www.researchgate.net/profile/Marcus_Wendin/publication/317616603_LCA_of_PVC-free_blood_bag_Sweden_PVCFREEBLOODBAG-LIFE_CYCLE_ASSESSMENT/links/59439e11a6fdccb93ab560e9/LCA-of-PVC-free-blood-bag-Sweden-PVCFREEBLOODBAG-LIFE-CYCLE-ASSESSMENT.pdf

The project also raised awareness of the negative health effects of certain chemicals used in healthcare sector and considerably increased the demand for alternative PVC-free devices. One of the most significant factors responsible for its success was the participatory approach employed by its initiators: the PVC-free blood bag was demanded and assessed by procurers involved in project and was produced by participating companies. Such an approach also allowed for sharing ideas and drawing from the knowledge and experience of the partners. The project initiators were also actively engaged in the process of advocating for stricter legislation concerning medical devices and contributed to the presentation of the European Commission's proposal on Medical Devices demanding prohibition of using harmful chemicals in medical devices in 2013.³⁹

Whilst the project has recently ended, the generated potential continues to be utilised; Karolinska University Hospital, along with two European manufacturers is currently preparing for the PVC-free blood bag to be introduced to the market, with funding from the Stockholm County Council Innovation Fund.⁴³

⁴³ Karolinska University Hospital (2018). Karolinska Takes the Next Step for PVC-free Blood Bag. Posted on April 10th, 2018. Retrieved from: <https://www.karolinska.se/om-oss/miljo-hallbarhet/pvc-fria-blodpasar/>

3. Stockholm County Council

In order to reduce the negative environmental impact of harmful chemicals, Stockholm County Council developed a strategy to limit or fully eliminate the use of certain groups of chemicals in different areas of activity. This strategy is based on a phase-out list of chemicals, which is mandatory when procuring for all County Council operations, including healthcare. According to the most updated version of the list (2017), there are 53 substances included within 4 substance groups within the medical devices and related consumables category (Table 2).⁴⁴

Substance name	CAS number	Reason for phasing out
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and liner	68515-50-4	Candidate, Suspected endocrine disruptor
Benzyl butyl phthalate (BBP)	85-86-7	Candidate, Endocrine disruptor
Di(2-thylhexyl) phthalate (DEHP)	117-81-7	Candidate, Endocrine disruptor
Di(2-methoxyethyl) phthalate	117-82-8	Candidate, Suspected endocrine disruptor
Di (branched C6-C8) alkyl phthalates	71888-89-6	Candidate, Suspected endocrine disruptor
Di (branched and straight C7-C11) alkyl phthalates	68515-42-4	Candidate, Suspected endocrine disruptor
Dibutyl phthalate (DBP)	84-74-2	Candidate, Endocrine disruptor
Di-C6-C10-alkyl phthalate and di-C6,C8,C10-alkyl phthalate	68515-51-5, 68648-93-1	Candidate, Suspected endocrine disruptor
Di hexyl phthalate, DHP	84-75-3	Candidate, Suspected endocrine disruptor
Diisobutyl phthalate (DIBP)	84-69-5	Candidate, Endocrine disruptor
Diisodecyl phthalate (DIDP)	68515-49-1, 26761-40-0	Suspected endocrine disruptor
Diisononyl phthalate (DINP)	28553-12-0	Suspected endocrine disruptor
Di-n-octyl phthalate (DNOP)	117-84-0	Suspected endocrine disruptor
Dipentyl phthalate (DPP)	131-18-0	Candidate, Suspected endocrine disruptor

Table 2: Stockholm County Council chemicals phase-out list based on the example of phthalates⁴⁴

⁴⁴ Stockholm County Council (2017). Phase-out List for Chemicals Hazardous to the Environment and Human in Products. Stockholm, Sweden: Stockholm County Council. Retrieved from: https://www.sll.se/globalassets/6.-om-landstinget/hallbarhet/miljo/utfasningslista-kemikalier/phaseout_list_products_web_eng.pdf

PVC elimination policy

The council have put special emphasis on reducing PVC in healthcare settings; in 1997, the Council decided to phase out the use of PVC in healthcare over health and environmental concerns. An investigation carried out before this decision showed that PVC in the healthcare sector was most abundant in gloves (Table 3). Under the 1997 commitment, the use of PVC-containing products has been progressively phased out, and not just in the healthcare sector.⁴⁵

	Buildings	Transport	Office materials	Healthcare
Flooring	50 tonnes	30 tonnes		
Wiring	35 tonnes			
Gloves				170 tonnes (18.8 million items)
Infusion devices				15-20 tonnes (580 000 items)
Urine bags				13 tonnes (450 000 items)
Total	100 tonnes	No data	No data	> 200 tonnes

Table 3: Amount of PVC supplied to Stockholm County Council (1997 and 2004)⁴⁵

Implementing this strategy was possible through engaging local and national authorities. The phase-out strategy covers different classes of chemicals including PVC, phthalates, BPA, mercury, and glutaraldehyde. Some of the substances are to be phased out (e.g. BBP, DBP, or DEHP), while others are to be reduced (BPA, DIDP, DINP, DNOP, and other phthalates). Devices and products contain such chemicals to be eliminated or limited can only be purchased under exceptional circumstances.⁴⁶ One of the most successful examples of this strategy is the substitution of examination gloves and flooring containing PVC within the Council's healthcare facilities. In cases where it is impossible to eliminate phthalates, they are replaced with alternatives.⁴⁷ Different substitutes for phthalates are being tested, with COMGHA, DINCH, and DEHT as the most promising alternatives, and as shown this does not necessarily incur greater costs (Table 4).⁴⁷

⁴⁵ Vesterberg, A., Hedenmark, M., & Vass, A.-M. (2005). PVC in Medical Devices. An Inventory of PVC and Phthalates Containing Devices Used in Healthcare. Final Report. Stockholm, Sweden: Karolinska University Hospital. Retrieved from: https://noharm.org/sites/default/files/lib/downloads/pvc/PVC_Med_Devices_Karolinska.pdf

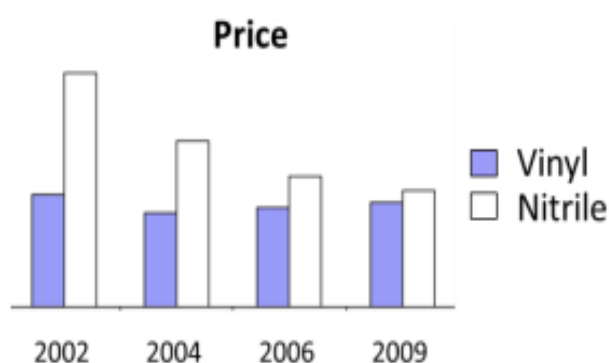
⁴⁶ HCWH (2014). Non-Toxic Healthcare: Alternatives to Phthalates and Bisphenol A in Medical Devices. Retrieved from: https://noharm-europe.org/sites/default/files/documents-files/3192/HCWH_Europe_report_-_Non-Toxic_Healthcare.pdf

⁴⁷ Jonsson, H. (2016). EDC Substitution. Examples from the Healthcare Sector [Presentation]. Stockholm, Sweden: Stockholm County Council. Retrieved from: https://noharm-europe.org/sites/default/files/documents-files/4410/2016-11-09_Hanna_Jonsson_-_EDC_substitution_-_examples_from_the_healthcare_sector.pdf

Product	Year	Price vinyl product	Price PVC-free product	Price PVC-free product (2016)	Difference
Examination gloves (nitrile)	2003	0,23	1	0,21	± 0%
Straight suction catheters	2007	1,05	2,45	1,95	+ 100%
Urinary catheters	2003	10,50	13,00	10,50	± 0%

Table 4: Comparison of prices between PVC-containing and PVC-free devices (as of 2016)⁴⁷

The largest amount of PVC in healthcare settings is found in gloves, they therefore became a target of another phase-out project conducted at the Stockholm County level. In 2004, the Council introduced a programme to gradually eliminate the use of examination gloves containing PVC from its healthcare facilities. According to the adopted procurement guidelines, not only should gloves not contain PVC and phthalates, but latex or powders that can cause allergic reactions are also not allowed; gloves containing nitrile, neoprene, and polyurethane are recommended substitutes.⁴⁶ As a result of this programme, not only have PVC gloves been substituted, but the price of nitrile gloves has significantly decreased as well. Medical devices with favourable environmental performance are expected to continue decreasing in price as demand increases. As Stockholm County Council illustrates, the price of nitrile gloves dropped by more nearly 50% between 2002 and 2009 (Graph 4); a similar trend can also be observed with infusion units used by the County as well.⁴⁸



Graph 4: Price progress of vinyl and nitrile gloves at Stockholm County Council (2002-2009)⁴⁸

⁴⁸ Dalenstam, E., Tordnell, N., Azzopardi, M., Sennstrom, L. (2012). Technical Report - Criteria for Sustainable Medical Devices. The Swedish Environmental Management Council Report 2012. Retrieved from: http://cocir.org/fileadmin/5.5_Policies_Environment/GPP/msr_2012_TR_health_care_EEFinaldraft_proofed.pdf

The success of the County's chemicals elimination strategies can largely be attributed to dialogue and engagement with medical device suppliers and manufacturers as part of the procurement process; communicating a clear message, based on transparent procedures, has also helped with harmonisation. Furthermore, regular assessments of procurement arrangements help obtain accurate data upon which purchases can be easily justified or questioned. Finally, introducing County-wide programmes are greatly influencing the purchasing power of procurers, leading to a considerable reduction of costs.

Statement of interest

The authors declare not to have any conflicts of interest regarding this article.

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