

# **SCOPE Work Package 4 ADR Collection**

**Collaboration with  
Patient Organisations  
to Promote and  
Support Patient  
ADR Reporting**



**SCOPE**

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### Authors

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We would also like to sincerely thank our colleagues from the French National Agency for Medicines and Health Products Safety (ANSM), the Danish Medicines Agency (DKMA), the Netherlands Pharmacovigilance Centre (Lareb) and the Medicines and Healthcare Products Regulatory Agency (MHRA), who have actively contributed to the development of this document.

## 1. Introduction

### 1.1 Purpose of the document

The purpose of this document is to promote the importance of cooperation between NCAs and patient organisations, to identify the main aspects of the process and to provide examples of good practice among MSs.

### 1.2 Background

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action has been created to support operations of pharmacovigilance (PV) in the European Union (EU) following the requirements introduced by the 2010 European PV legislation<sup>1,2,3</sup>, which came into force in June 2012. Information and expertise on how regulators in Member States (MSs) run their national PV systems was gained in order to develop and deliver guidance and training in key aspects of PV, with tools, templates and recommendations. The aim of the SCOPE Joint Action was to support consistent approach across the EU network for all PV operations, in order to benefit medicines safety monitoring and communications to safeguard public health.

SCOPE was divided into eight separate Work Packages (WPs), with five WPs focusing on PV topics to deliver specific and measureable objectives, ranging from improvements in Adverse Drug Reaction (ADR) reporting to assessment of quality management systems.

WP4 ADR Collection was focused on national schemes for the spontaneous reporting of ADRs and was aimed to provide National Competent Authorities (NCAs) with a full understanding of and good practices within national systems for collecting ADRs. Information was gathered from European MS institutions to understand their national ADR system, PV IT system capabilities, as well as implementation of patient reporting, types of reporting forms developed, and electronic reporting developments, including those from clinical healthcare systems. This information was used to create best practice guidelines, performance indicators and a media toolkit for raising awareness of ADR reporting systems which will be supported through delivery of a training course for institutions.

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<sup>1</sup> Directive 2010/84/EU of the European Parliament and of the Council

<sup>2</sup> Regulation (EU) No 1235/2010 of the European Parliament and of the Council

<sup>3</sup> Commission Implementing Regulation (EU) No 520/2012

## 1.3 Definitions and abbreviations

Terminology	Description
ADR	Adverse Drug Reaction
ADHD	Attention Deficit Hyperactivity Disorder
AIDS	Acquired Immune Deficiency Syndrome
ANSM	Agence Nationale de Sécurité du Médicament et des Produits de Santé, French Medicines Agency
AMRC	Association of Medical Research Charities
DKMA	Danish Medicines Agency
DSU	Drug Safety Update
EMA	European Medicines Agency
EU	European Union
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
Lareb	The Netherlands Pharmacovigilance Centre
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare Products Regulatory Agency
MS	Member State
NCA	National Competent Authority
NPCF	Patiëntenfederatie Nederland
OACS	Organisation for Anti-Convulsant Syndrome
PCWP	Patients' and Consumers' Working Party
PGCF	Patient Group Consultative Forum
PR	Public Relations
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
WP	Work Package

## 2. Collaboration with patient and consumer organisations

### 2.1 SCOPE survey results

One of the goals of the WP4 was to identify methods of engaging different stakeholders in the healthcare system in ADR reporting. Patients and patient organisations are very important stakeholders in this process and there were several questions in the WP4 questionnaire related to this issue.

Based on SCOPE survey results, 57% of MSs (16/28 respondents) do not work with any patient organisation in order to promote or support patient ADR reporting. Remaining 12 MSs (43%; 12/28 respondents) collaborate with patient organisations in order to promote or support patient ADR reporting, predominantly in the following way: making reporting available through links on patient organisation webpages (66%; 8/12), links on patient forums (25%; 3/12) or having patient organisations collecting patient ADRs directly from patients (33%; 4/12).

The number of specific patient organisations different MSs work with (75%; 9/12) varied from one to 20. Some MSs stated that they collaborate either with all major patient organisations within their country, or with one 'umbrella' patient organisation, which is representing all patient organisations. Most often they collaborate with patient organisations dealing with chronic and serious diseases such as cancer, diabetes mellitus, multiple sclerosis and haematological diseases.

### 2.2 Patient empowerment

Patient empowerment is an important concept in healthcare. It concerns different aspects of disease management, including the domain of patient safety. People's experiences and perspectives are valuable resources for supporting optimal patient care and sustainable healthcare systems. In order to ensure self-help and mutual aid, individual patients engage in the work of patient organisations, usually concerned by a specific health problem. In this way, patient organisations become an important link between patients on one side and different stakeholders in the healthcare system, including NCAs, on the other side.

NCAs and patient organisations share many common goals and can collaborate effectively to help meet patient's needs. Patient organisations help regulators understand what it is like to live with a disease, the challenges patients and their families are facing, the weak points of the system and the difficulties they might have in reporting adverse reactions, including the consequences of adverse reactions related to the disease therapy. By collaborating with NCAs, patient organisations can advocate for patients' needs. They also expect to gain reliable, scientifically based information on medicines and to improve the efficacy of the system (e.g. a prompt response by NCAs).

Patient organisations can help NCAs to reach patients, their carers and the wider public and to build patient awareness, understanding and engagement on the important aspects of disease management, including management of ADRs. Interacting with patient organisations enables NCAs to learn about and understand barriers to treatment success, and can also help identify the best methods to engage patients. The scope of collaboration with patient organisations can range from raising awareness to specific health issues, such as antibiotic resistance, to engaging patients in ADR reporting. Promoting and supporting patient ADR reporting is the specific focus of this document.

Patient ADR reporting can be facilitated by the cooperation of NCAs with patient organisations. This may refer to raising awareness among patients about the importance of patient ADR reporting in ensuring patient safety, taking into account patient reservations about the relevance of their particular ADR report within the product lifecycle. In addition, patient organisations can help NCAs to understand patient concerns and motivations. Patient organisations can also help identify and promote viable methods for patient reporting by engaging in the development of patient reporting forms, providing links to the electronic ADR forms on their websites, educating patients on how to prepare and send the ADR report and helping patients to understand the importance and consequences of ADR reporting.

Taking all this into consideration, it is somewhat surprising that according to the SCOPE survey results more than 50% of MSs do not collaborate with patient organisations with regard to patient ADR reporting. In order to enhance cooperation between patient organisations and NCAs, in relation to patient ADR reporting, key points of the process were described in this document, ranging from highlighting the importance of a strategic approach to cooperation with patient organisations, to practical day-to-day aspects of the cooperation, including examples of good practice recognised between MSs as well as patient and consumer organisations' view on collaboration.

## 2.3 Patient and consumer organisations' view on collaboration

In order to promote the importance of collaboration with patient organisations, this document contains the views and opinions of several European patient and consumer organisations: [Test-Achats](#), [European Heart Network](#), [Health Action International](#) and [International Patient Organisation for Primary Immunodeficiencies](#). Their input can enhance understanding of the expectations that patient organisations have when collaborating with NCAs.



Although the organisations differ in some relevant aspects (e.g. type of patients being represented, diseases being covered) and in their scope (patients organisations are more disease-focused, while consumer organisations have a public health approach) the answers they provided indicate certain common points of interest: the importance of collaboration with NCAs in the promotion of patient ADR reporting, patient input in the optimisation of patient ADR reporting forms, tools and patient reporting process, and the importance of using lay language in the presentation of medical information.

Both patient and consumer organisations have stressed that, together with NCAs, they can collaborate to promote patient ADR reporting and motivate patients to engage in this activity. These organisations can promote direct patient reporting on their websites, magazines and other ways of interaction with their members, to have a bigger outreach. In their opinion, these initiatives have the advantage of transmitting more understandable and less technical information to patients. In addition, they might have a broader impact, thanks to the constant interaction with patients and through the various channels they utilise. Moreover, patients find patient and consumer organisations more approachable in comparison with NCAs. Additionally, promotion of ADR reporting should be supported by sustained national media campaigns to ensure that the whole population is targeted and informed about the need for ADR reporting. According to patient and consumer organisations, a common campaign with NCAs, for instance, would be interesting.

While promoting ADR reporting, NCAs should bear in mind the specificities of the medicines (i.e. patients receiving biological products, such as immunoglobulin, will experience ADRs depending on the specific immunoglobulin they receive each time) so as to ensure that patients feel the reporting takes into account their specific case. This direct communication with patient organisations should be reinforced by targeting healthcare specialists, as it can be the case, particularly for patients with rare diseases, that the specialist is the only person the patient knows that is aware of the disease.

Finally, it is important to give patients and organisations feedback when they report ADRs. In this way, ADR reporting can start being perceived as a common practice and, hence, can be encouraged. Furthermore, transparency is necessary about reported ADRs and about the results of reporting, such as detection of new ADRs. This transparency is an incentive to report ADRs. By informing their members about different outcomes of ADR reporting, consumer and patient organisations may further accentuate the importance of ADR reporting.



Any information intended for patients should be in lay language and if possible delivered through various channels and formats. Channels for reporting ADRs should be adjusted to different patient populations. It is very important to develop simple and easy to use tools, so patients or patients' close relatives can report ADRs directly, without taking much time. Patient and consumer organisations are willing to help NCAs with reporting forms and with the development of different reporting applications. They can review and give feedback on the reporting form used by the NCAs, and on the way they plan to promote patient reporting, to ensure everything is formulated in a reader-friendly way. It should be taken into consideration that younger patients can find web-based applications or mobile applications attractive, but they can be quite complicated for older patients. Patient organisations representing older (multi)morbid patients stressed that filling ADR reporting forms can be very difficult and complicated. They are not sure if an elderly person will feel confident enough to follow the reporting procedure or even have the knowledge about the possibility to report online. This patient population should be informed by pharmacists and doctors about ADRs and the possibility of reporting them back to pharmacists or doctors. ADR reporting forms available in pharmacies or general practitioner offices could also be of use.

Patient and consumer organisations in some instances publish magazines in lay-language and inform patients about the latest therapies, lifestyle information and the possibilities of a personal medical consultation. In some instances, especially in relation to urgent safety information, these organisations may facilitate passing important information (i.e. by publishing) to patients in lay-language.

## 2.4 Targeting patient organisations

The first step for NCAs in establishing collaboration with patient organisations should be the targeting of patient organisations. However, the question arising from this is how best to identify these patient organisations. In some MSs, there are organised systems providing information about existing patient organisations – for example, lists of all patient organisations in the country provided on the webpages of the Health Authorities; existing registries of patient organisations, or specific routing companies with contact details of patient organisations. However, there are countries where this information cannot be systematically obtained. Therefore, each MS should establish what would be the best possible way to have an overview of all the existing patient organisations in their country, depending on the local situation.

Furthermore, in case there is an existing registry of patient organisations in the MS, the important thing is to learn if the registry data is publicly available and/or if this data can be used by NCAs. In some MSs collaboration with patient organisations is a part of the strategic NCA documents that may serve as a guide in many aspects of collaboration. Moreover, there are different types of patient organisations. Some organisations are organised related to the specific disease and some patient organisations are 'umbrella' organisations which comprise more patient organisations. These points have to be taken into account when establishing collaboration with patient organisations. Finally, for the purposes of good communication and channelled exchange of information, contact persons within both patient organisations and NCAs may be appointed.

## 2.5 Eligibility criteria

From the experiences of different MSs, it can be concluded that some NCAs have specific eligibility criteria when deciding on collaboration with patient organisations, whilst in some countries, collaboration is developed without taking into account any specific eligibility criteria. This different approach might be due to the fact that collaboration with some patient organisations are financed, hence the need for establishing certain criteria. When deciding about the criteria that a patient organisation needs to fulfil to be eligible for collaboration with the NCA, the NCA may wish to take the following points into consideration:

- Does the patient organisation need to be registered (and if yes, where)?
- Does the patient organisation need to have its mission/objectives defined and/or published?
- Is there a specific structure that patient organisations need to have? Are there specific requests for the governing bodies?
- Does the patient organisation need to have a specific interest in medicinal products?
- Does the patient organisation need to disclose to the NCA its sources of funding, both public and private?
- Do patient organisations need to disclose conflicts of interest to the NCA?

There are different types of patient organisations, so the NCA may wish to collaborate with individual patient organisations (e.g. with disease-specific patient organisations) or with 'umbrella' organisations (comprising more patient organisations) depending on the objective of the collaboration to be established. Moreover, it is advisable to reflect on the area in which the organisation is active, its maturity, influence, size, etc.

## 2.6 General guidelines and conclusions

In general, a proactive approach is advised when establishing a collaboration with a patient organisation, but in case the NCA is being approached by the patient organisation, the internal process should also be defined. Continuous cooperation as well as collaboration on case-by-case basis should be encouraged. Furthermore, NCAs may approach more than one patient organisation for the same reason (e.g. to promote patient reporting) or there are some specific objectives related to the type of patient organisation, which need to be addressed differently (e.g. approaching the organisation of patients with organ transplants regarding the safety of immunosuppressants).

The scope of collaboration may extend from the promotion of patients' ADR reporting to, for example, education on the safety of medicines. The interests of patient organisations and of the public in general should also be explored, and the collaborating objectives adapted accordingly. Moreover, NCAs may consider involving patient organisations in regular NCA activities (e.g. involvement in scientific committees, input on educational materials aimed at patients, patient information leaflets or other NCA documents intended for the public). In some NCAs, there are also Patient Expert Advisory Groups or equivalent groups, which contribute to better collaboration between the NCA and patient organisations and facilitate further activities planning.

Finally, the impact of collaboration on the national PV system, national healthcare system, the NCA and patient organisations themselves should be measured in order to detect good practices and to improve in areas where practices prove to be insufficient or inadequate. Therefore, NCAs should consider and plan the best way to measure the impact of collaboration with patient organisations.

In conclusion, presenting information on collaboration with patient organisations to the interested public (e.g. publishing highlights on the NCA website) will contribute to the transparency and improve the public health as well as patients' engagement and awareness.

## Annex 1. France – French National Agency for Medicines and Health Products Safety (ANSM)



The French National Agency for Medicines and Health Products Safety (ANSM) has collaborated with patient organisations since 2006. This collaboration has been reinforced since 2012. ANSM collaborates with all kinds of patient organisations, regardless of maturity, size or influence. The core network includes umbrella organisations, like Acquired Immune Deficiency Syndrome (AIDS)/ Human Immunodeficiency Virus (HIV) and other infectious disease umbrella organisations, organisations for cancer, neurodegenerative diseases, rare diseases, mental disorders, diabetes, and rheumatologic diseases, but also organisations of consumers and families.

ANSM has recognized patient organisations as key stakeholders. The purpose of interaction is to maintain transparency and reinforce dialogue with the aim of building public trust in ANSM. ANSM provides patient organisations with information and seeks their advice. This advice is taken into account, alongside advice from other stakeholders, such as advice obtained from healthcare professionals. Patient organisations are providing real life information about patient management. ANSM expects patient organisations to spread information obtained from ANSM through their network.

On the ANSM website there is a section dedicated to collaboration with patient organisations named ANSM and patients organisations: a reinforced partnership ([http://ansm.sante.fr/L-ANSM2/L-ANSM-et-les-associations-de-patients/Un-partenariat-renforce/\(offset\)/0](http://ansm.sante.fr/L-ANSM2/L-ANSM-et-les-associations-de-patients/Un-partenariat-renforce/(offset)/0)). This states that patient organisations have been able to report ADRs since 2010. Ever since, ANSM closely works with them to improve both the quality and number of reports. In the ANSM annual report of 2014 ([http://ansm.sante.fr/content/download/81673/1033191/version/1/file/ANSM\\_Rapport-Annuel-2014\\_Anglais.pdf](http://ansm.sante.fr/content/download/81673/1033191/version/1/file/ANSM_Rapport-Annuel-2014_Anglais.pdf)), Annual Information Day with patient associations, is described (p. 107-108). Moreover, annual calls for projects are described in the same document (p. 118-119).

ANSM collaborates with patient organisations for specific diseases and with umbrella organisations, such as Inter-Association Collective on Health (which consists of 42 organisations), or consumer associations such as the Union of French Consumers. When searching for collaboration, ANSM is targeting those patient organisations that are labelled with a 'national agreement'. This label is given by the French Ministry of Health and is based on certain criteria. The list is published online on the Ministry's website: [http://social-sante.gouv.fr/IMG/pdf/associations\\_agreees\\_france-3.pdf](http://social-sante.gouv.fr/IMG/pdf/associations_agreees_france-3.pdf). In March 2016, 119 patient organisations were on this list. Furthermore, ANSM identified a number of other patient organisations willing to collaborate but that don't have this label (for example, newer organisations). Besides using this list, when ANSM is aiming at wider audience it uses a routing company named Celtipharm. This company has a contact list of 8000 patient organisations.

Collaboration is requested or accepted by ANSM according to the patient organisation's profile, type of interaction and regulatory framework. For events dedicated to patient organisations, such as workshops about ADRs reporting, the framework is more informal and any organisation is invited regardless of its profile. By contrast, to become a member of a consultative committee of ANSM or of the Interface Committee between patient organisations and ANSM, the organisations who have answered to a call for candidates are elected by a jury of external and internal members for three years.

There are certain criteria that ANSM uses to determine whether or not to engage with a patient organisation. The patient organisation needs to be a representative of the patient population through its actions, positioning and/or number of members; its actions need to be in favour of public health; and it shouldn't have conflicts of interest (according to the topic dealt with and the frame of interactions). To be a member of the ANSM board or Committee, National approval in health is requested. Otherwise, for collaboration with ANSM, a patient organisation doesn't need to be registered elsewhere, but does need to have its mission/objectives defined. They are described in official articles of incorporation, filed by the authorities when a non-profit organisation is created. The article of incorporation specifies the objectives of the organisation, the management bodies, the representative person, and the address. For collaboration with ANSM, a patient organisation doesn't need to have a specific interest in medicinal products; it only needs to be interested in the safety of medicinal products or medical devices in general. Therefore, a few of the organisations ANSM works with represent families, consumers or people involved in environmental diseases. The collaboration concerns a wide range of areas: clinical trials, shortages, PV, medical devices, etc. The patient organisation needs to disclose to ANSM its sources of funding, both public and private. When the organisation is involved in a decision process, the declaration of links and conflicts of interests are published on the ANSM website. Previously, they are analysed by ANSM's Deontology department.

ANSM involves patients and patient organisations in different areas of their work. Patients are integrated in ANSM's consultative committees (two representatives in each of the three committees) and administrative board (two representatives). These were constituted after a call for candidates. The Interface Committee between ANSM and patient organisations is, together with two others (for healthcare professionals and the pharmaceutical industry), also constituted within ANSM after a call for candidates. It consists of seven members from different patient organisations and seven ANSM representatives.



Topics they are dealing with are clinical trials and access to innovation, reporting of side effects by patients, re-assessment of benefit/risk ratio, deontological aspects, shortages, etc. Minutes of the meetings are published online. Within the Interface Committee are two working groups: the Patient information working group and the Medicines used in paediatrics working group. The first is constituted of seven organisations and the second of 14. The Patient information working group is involved in activities relating to review of communication supports, internet website and general topics, including diffusion of ANSM information, impact of communication and adaptation to special needs (patients with mental diseases, disabled people, etc.). The Patient information working group also reviews communication materials intended for larger audiences or the general public. If the topic of communication material is specific, then it is reviewed by the patient organisation concerned. The Patient information working group also reviews guidelines about medicine box labels, ahead of the public consultation.

There is a dedicated person within ANSM, a doctor of pharmacy specialised in communications and public relations, who defines strategy for approaching patient organisations. This person also approaches patient organisations, by telephone or email, when the strategy is approved by the managing director and often sets up a first teleconference or a meeting at the ANSM. The contact person within a patient organisation could be the president, director, scientific referent or person responsible for communications. To establish cooperation with a new patient organisation takes anything from a couple of hours to a few days, according to the context and issue. Collaboration with patient organisations takes 0.80 Full Time Equivalents of one dedicated person within ANSM. Once established, collaboration with the patient organisation is usually permanent. There is a budget within ANSM allocated for collaboration with patient organisations. It is €175,000 for 2016, which is considered sufficient for planned activities.

As mentioned before, ANSM has organised an Annual Information Day with patient associations since 2012. These meetings are an opportunity for the ANSM to get to know the representatives of patient organisations and have so far been attended by 100 participants and 80 patient organisation representatives. At these meetings, patient organisations' representatives are informed how to report ADRs. They are also invited to educate patients on how to report ADRs, using the information available on the ANSM website. Dedicated workshops are organised at these events with the participation of the representatives of Pharmacovigilance Regional Centres. At the end of each Annual Information Day with patient associations a satisfaction questionnaire is circulated. Results of this satisfaction questionnaire are published.

Meetings between patient organisations and ANSM directors and/or internal experts are also organised, upon request from the organisation or proactive suggestion of ANSM. These meetings are also an opportunity to educate patients about ADRs reporting.

ANSM publishes calls for patient organisations' projects each year and provides financial resources for these projects; projects supporting ADR reports by patients are explicitly encouraged. Through a yearly call for projects (around €150,000 each year), ANSM provides financial support of up to €50,000 per project. Some projects are aimed at educating patients for the reporting of ADRs. Here are some examples of projects funded by ANSM:

- Enhancement of reporting of adverse effects of medicines and medical devices by patients by the French multiple sclerosis patients' association (2012, €35,656)
- A project on self-reporting of adverse effects due to exposure to diethylstilbestrol (DES) in utero by the DES Network (2012, €40,000)
- Reporting of adverse effects due to the use of coagulation factors in patients with haemophilia and other rare coagulation disorders by the French haemophilic patients association together with healthcare professionals (2013, €23,600)
- Announcement of the grant: <http://afh.asso.fr/L-AFH-remporte-l-appel-a-projet>
- Videos on YouTube:
  - <https://www.youtube.com/watch?v=FbhXPSSPYRo>
  - <https://www.youtube.com/watch?v=cRLHFKuNQEc>
- Accompanying service of patients for self-reporting of adverse effects linked to the use of medicines in rare diseases by Rare diseases Info Services (2013, €15,200)
- Webpage: <http://www.maladiesraresinfo.org/effets-indesirables-info-services.html>
- Series of videos on YouTube: [https://www.youtube.com/channel/UCGDbPtHM1LEV1GdvK8KF\\_Gg](https://www.youtube.com/channel/UCGDbPtHM1LEV1GdvK8KF_Gg)
- Surveillance of patients during hormonotherapy in breast cancer by Seintinelles (2013, €30,000)
- Implementation of a self-evaluation system for behavioural disorders induced by anti-Parkinson medication by France Parkinson Association (2014, €20,000)
- Analysis of discussions about drug treatments between patients with renal diseases, on dialysis and transplanted patients on the Renaloo Forum and other social media (2015, €35,000)
- Project «All knowing=All responsible=All vigilant?» by Restart Association (Bone marrow transplanted patients) (2015, €19,000).



Results of the call for projects towards patient organisations in 2015 are published on the ANSM website: [http://ansm.sante.fr/L-ANSM2/Appels-a-projets-Associations/Appel-a-projet-Associations-d-usagers-du-systeme-de-sante-2015-Resultats/\(offset\)/0](http://ansm.sante.fr/L-ANSM2/Appels-a-projets-Associations/Appel-a-projet-Associations-d-usagers-du-systeme-de-sante-2015-Resultats/(offset)/0). Patient organisations sometimes publish results of collaboration; this is required if they have received financial resources.

Regarding the challenges they have encountered, ANSM considers that better handling of requests/needs from both sides is still necessary and that organising more hearings in commissions and working group meetings is also warranted.

Patient organisations provide ANSM with valuable information and insights (real-life testimony about ADRs, effects of shortages or treatment switch, understanding of information given by health authorities and healthcare professionals). Some decisions were made taking into account the hearings of patient organisations (relating to withdrawals, early access, choice of alternative solutions when coping with shortages, information reinforcement, etc.). Furthermore, patient organisations can adapt messages obtained from ANSM to the target audience with which they are more familiar. ANSM provides explanations to patient organisations about medicinal products' issues, which seems to be highly appreciated by patient organisations.

## Annex 2. Denmark – Danish Medicines Agency (DKMA)



The SCOPE survey completed by MSs has shown that the Danish Medicines Agency (DKMA) collaborates with all major patient organisations (cancer, heart diseases, diabetes, rheumatoid diseases, etc.). In Denmark, reporting of suspected ADRs is available through links on patient organisation webpages. The DKMA also holds meetings with patient organisations to discuss reporting issues.

The DKMA doesn't have any specific strategy document for collaboration with patient organisations. Instead, collaboration with patient organisations is usually incorporated into a general action plan in the PV area. The aim of collaboration is to ensure a good process in which all relevant parties feel that they are involved and listened to, ultimately leading to the communication of relevant information to the right patients.

There is no specific budget allocated to collaboration with patient organisations within the DKMA. Collaboration with patient organisations is not formalised, but the DKMA involves patient organisations in their work as far as possible. The DKMA collaborates with every relevant patient organisation, including disease-specific patient organisations and 'umbrella' organisations, regardless of size and influence. The patient organisation doesn't need to have a specific interest in medicinal products to establish the collaboration. Furthermore, patient organisations don't need to disclose conflicts of interest to the DKMA.

A list of all patient organisations in Denmark is maintained on the [official health webpage](#). It is generally the DKMA that approaches the patient organisations and this approach is usually proactive. If DKMA activity is focused on a specific disease area or a specific group of patients, where possible the DKMA invites specifically relevant patient organisations to collaborate. Depending on the nature of the action/campaign, the DKMA contacts patient organisations by email or telephone. If it is a larger campaign, the DKMA usually starts by performing a feasibility study in the form of interviews or surveys among the patient organisation members. Collaboration with patient organisations is not on a continuous basis, but rather on a case-by-case basis. The reverse situation, patient organisations approaching the DKMA, is not common.

Collaboration with patient organisations generally involves PV safety issues. The purpose of collaboration is to gain knowledge about the relevant patient group in order to ensure that the information and messages are as targeted and adapted to the recipients as possible. This leads to the communication of relevant information to the right patients. The DKMA, in the scope of collaboration, launches activities on social media, websites or in journals, or creates leaflets and videos. It is typically the same type of action, although it would depend on the nature of the action and the purpose of the task. The DKMA doesn't provide financial or other support (e.g. education on safety of medicines) to patient organisations. Patient organisations are not involved in regular DKMA activities, nor are members of any DKMA scientific group, but patients are involved in the preparation of various information materials when they are aimed at a specific group or groups.

The DKMA is responsible for the preparation of educational/information material intended for patients, but this is carried out in collaboration with the relevant patient organisations. The patient organisations provide their input on the form and content of the material and also help the DKMA to distribute it. If, for example, the DKMA is making a video, representatives from the relevant patient organisations may appear in that video.

There are no dedicated personnel within the DKMA for collaboration with patient organisations. When pharmaceutical safety measures are required, a staff member from the Pharmacovigilance Division contacts the patient organisation. The contact person within patient organisations is the one who is responsible for disseminating information to the members of the organisation and finding members to engage in the concept development of actions/information campaigns as needed.

The DKMA considers that collaboration with patient organisations brings added value to their work. As a result of that collaboration, the communication of safety information became more targeted and relevant to the patients concerned. The DKMA doesn't measure the impact of collaboration on their work, but they get positive feedback from the patient organisations.

## Annex 3. The Netherlands – The Netherlands Pharmacovigilance Centre (Lareb)



The Netherlands Pharmacovigilance Centre (Lareb) collaborates with umbrella organisations as well as disease-specific patient organisations. The aim of collaboration is to raise awareness of ADRs; to raise awareness of what Lareb does and encourage patients to report ADRs; to gain in-depth knowledge about drug use and ADRs in certain patient populations with the same disorder or disease; and to provide signals or strengthen ‘near’ signals from Lareb.

In Lareb’s strategic business plan for 2015-2019, the collaboration with patient organisations is highlighted. In this period, Lareb aims to further strengthen the collaboration with patient organisations and healthcare professionals and to raise awareness among the general public about the possibility and importance of ADR reporting. Lareb doesn’t have specific budget allocated to collaboration with patient organisations. Funding does not allow Lareb to do nationwide Public Relations (PR) campaigns, but they think that with the resources they have it is still possible to achieve quite a lot. Furthermore, Lareb doesn’t provide any financial support to patient organisations. At the moment Lareb doesn’t use any eligibility criteria when cooperating with patient organisations. Depending on the type of question/need, they consider if cooperation is possible.

In the past years Lareb has collaborated with Patiëntenfederatie Nederland (NPCF), which is an umbrella patient organisation. They have also worked with disease-specific patient organisations, such as Impuls & Woortblind (the patient organisation for patients with attention deficit hyperactivity disorder, attention deficit disorder, dyslexia and dyscalculia), Crohn and colitis ulcerosa vereniging Nederland (the patient organisation for patients with Crohn’s disease and ulcerative colitis), Schildklier Organizatie Nederland (the patient organisation for patients with thyroid disorders) and Consumentenbond (the main consumer organisation in the Netherlands).

Lareb collaborates with patient organisations in a proactive as well as reactive manner. Regarding proactive collaboration, Lareb tries to work with larger patient organisations. They have a good collaboration with NPCF, which is an umbrella organisation consisting of more than 160 patient organisations. If Lareb needs additional information about a certain ADR, they try to work with patient organisations whose members use medicinal products of interest. Regarding reactive collaboration, patient organisations can also approach Lareb. Lareb estimates, on the basis of patient organisations’ questions and needs, if collaboration is possible.



Lareb identifies patient organisations through the NPCF network, their own network or through the internet. When Lareb wants to target a specific patient organisation, they usually try to contact someone they know within that organisation. If this is not possible, Lareb tries to find the most suitable person, depending on the aim of the collaboration, either through internet or just calling/ mailing through the general contact details. Depending on the aim of the collaboration, it can be on a continuous (for example with NPCF and Consumentenbond) or on a case-by-case basis (Impuls & Woortblind, Crohn and colitis ulcerosa vereniging Nederland and Schildklier Organisatie Nederland).

Lareb has provided examples of activities performed in collaboration with patients' organisations. The collaboration with Consumentenbond consists of a column in their monthly magazine (34,000 printed copies). In this column Lareb describes ADRs of current interest. To raise general awareness about why and how to report ADRs, Lareb tries to work on their online presence on the patient organisations' websites. For example, they provide website news or a link to a reporting form. Lareb also tries to raise general awareness through articles in patient organisations' magazines. Sometimes, Lareb has booths at fairs where their target audience is present. They also give presentations for patient organisations, although this is quite restrictive since this is very time-consuming. Lareb has conducted a survey among members of the Impuls & Woortblind organisation, regarding a medicinal product's use and ADRs. Lareb helped the Crohn and colitis ulcerosa vereniging Nederland organisation to analyse a questionnaire regarding potential signals. Through that activity, Lareb invited members of that specific organisation to report ADRs. Furthermore, two representatives from patient organisations are part of the Lareb board. At the moment Lareb is creating a patient panel, which can advise them on communication materials and information on medicines, reporting forms, questionnaires, etc. Lareb would like to engage more with patient organisations. To reach the third aim (To gain in-depth knowledge about drug use and ADRs in certain patient populations), Lareb has to collect reports of adverse reactions. At this moment they are waiting for a technical solution that automatically imports the information necessary for the report form (the patient tool).

Depending on the aim of the collaboration with the patient organisation, the Lareb contact person varies from the director to someone working at the web redaction. Most of the contacts go through the Lareb communication team. They have one person who is the focal person for patient organisations and that person dedicates approximately one day a week for these activities. In addition, another person works on the website and another on developing PR and information materials.

Lareb considers that it is difficult to directly measure the value of the collaboration with patient organisations. Regarding the aim of creating awareness for ADRs and creating awareness of what Lareb does, in order to encourage patients to report ADRs, Lareb has conducted a general survey. This survey has showed that 17% of the population knew about Lareb. Although it is quite a low number, it is higher than in many other countries. In the last few years, the number of patient reports has increased in the Netherlands and today patients form the largest group of reporters. However, it is difficult to know how much of this increase is due to collaboration with patient organisations, the new legislation (in every patient information leaflet it is written that patients should report ADRs to Lareb) or the increased media presence of Lareb.

Regarding presentation of results and transparency, the results of the collaboration are primarily shown to the contact person of the patient organisation and they can choose how to further communicate this information within their organisations. The information is also shared through the Lareb website. If contributing to signal detection, the information is shared with the Medicines Evaluation Board.

Lareb has pointed out some challenges and limitations of collaboration with patient organisations. As Lareb and patient organisations sometimes have different 'cultures', both parties need to get used to how the other party works. Sometimes this is very challenging, especially when it comes to the communication of results. Another challenge is to give the collaboration a prominent place within the patients' organisation and the priority that it needs. Often it is seen as something extra and not a necessity.

As mentioned before, it is difficult to measure the impact of the collaboration with patient organisations. But, in the cases where collaboration has led to new information and signals, this has been important not only to Lareb and the patient organisations, but also to the PV system in general.

### **Lareb example on Collaboration with patient organisations to increase knowledge about drug use and side effects**

75% of the adults using medication for Attention Deficit Hyperactivity Disorder (ADHD) experiences side effects. The most frequently mentioned side effects are in the leaflets. In general, respondents experienced positive effects of the medication on their symptoms. Experiencing side effects or lack of effect can be a reason to stop medication use.

These are the results of a survey conducted in June 2015 by the Dutch Association for people with AD(H)D, dyscalculia and dyslexia, 'Impuls & Woortblind', in collaboration with the Netherlands Pharmacovigilance Centre Lareb, among users of ADHD medications who were 16 years or older.

This online survey was sent by e-mail to members of Impuls & Woortblind and to clients in two private practices. Also professionals who are members of the Dutch ADHD network could send the link of the survey to their clients. A total of 1160 respondents filled out the questionnaire and, after applying exclusion criteria, 848 of these could be used for further analysis. The questionnaire contained questions about the experiences with drug use and side effects and the received information about possible risks and side effects.

On the last page of the survey, the respondents were asked to report their experienced side effects to Lareb. All respondents who mentioned a side effect and provided their e-mail address to be contacted for further information were asked to report their side effects to Lareb. By the end of September 2015, 44 respondents had filed a report. None of these reports has led to further action.

Collaboration with patient organisations is important to raise awareness about PV among the general public. It can also be used to collect information about drug use and ADRs in a selected population.

The results of the survey are published on the Lareb website, including the full report in Dutch<sup>4</sup> and a summary in English<sup>5</sup>.

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<sup>4</sup> Ervaringen van volwassenen met ADHD medicatie. October 2015. Accessed: 30.03.2016., available from URL: [http://www.lareb.nl/getmedia/b00e34c6-8b28-4481-878b-35f05d072391/Lareb\\_rapport\\_ADHD\\_okt15\\_def.pdf](http://www.lareb.nl/getmedia/b00e34c6-8b28-4481-878b-35f05d072391/Lareb_rapport_ADHD_okt15_def.pdf)

<sup>5</sup> Adults' experiences with AD(H)D medications. Accessed: 30.03.2016., available from URL: <http://www.lareb.nl/getattachment/56af7c5e-e8dd-4bd9-9b52-58cc5532ec39/20160309-ENG-Summary-ADHD-report.pdf>



## Annex 4. The United Kingdom – Medicines and Healthcare products Regulatory Agency (MHRA)



The Medicines and Healthcare products Regulatory Agency (MHRA) has in place a Yellow Card Strategy which has the aim of increasing the number and quality of suspected ADR reports. A new communications strategy was devised to raise awareness of the Yellow Card Scheme in 2012. The drivers for the new strategy include: the 2012 PV legislation, the independent evaluation of patient reporting (the Health Technology Assessment (HTA) report by Avery et al<sup>6</sup>, and analyses of suspected ADR reporting figures. The Avery Report, in 2011, identified the importance of patient reporting for PV and recommended further promotion of the Yellow Card Scheme, which was taken forward through communication campaigns. The Avery report confirmed the MHRA's views, developed through internal analysis, about the added value and contribution of patient reporting to PV through the reporting of suspected ADRs.

In relation to this communication strategy, the MHRA has focused much of its campaigning efforts on targeting healthcare professionals, as the most trusted means of reaching patients, carers and parents. This is with the aim of encouraging healthcare professionals to raise awareness of ADR reporting among patients. The need for sustained communications and promotion is acknowledged by the MHRA as part of its Yellow Card strategy work. Recent initiatives have included the use of presenting the value and importance of reporting to the Yellow Card Scheme, for example through case studies.

Nationwide marketing campaigns included information videos and posters, displayed in general practice surgeries and pharmacy waiting areas, and the distribution of patient ADR information leaflets (which also include the patient reporting form) to pharmacies and general practice surgeries. To further promote the importance of reporting and to increase awareness, information about the Yellow Card Scheme has been communicated through posters and oral presentations at a range of external patient-facing meetings.

The Yellow Card Strategy and communication campaign efforts have resulted in a number of collaborative partnerships. As a consequence, correct information about ADR reporting is available online, so patients can access such information from trusted sources, for example from: [www.patient.co.uk](http://www.patient.co.uk), NHS Choices, BootsWebMD, Medicines for Children, which is aimed at parents, young people and their representatives, and the annual 'Ask your Pharmacist Week' campaign. Information is regularly reviewed for accuracy and content is updated. This is done by a member of the PV staff whose role is primarily related to the Yellow Card Strategy.

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<sup>6</sup> Avery, AJ et al. (2011). Evaluation of patient reporting of adverse drug reactions to the UK Yellow Card Scheme: literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technology Assessment, 15 (20), doi: <http://dx.doi.org/10.3310/hta15200>

Moreover, contacts have been made with numerous patient-facing organisations that have product information published on their websites. Consequently, they also published information about ADR reporting to the Yellow Card Scheme. It is in a similar and recognisable style that is now mandatory for paper patient information leaflets. In addition, a blog has been written for an umbrella patient organisation called the Association of Medical Research Charities (AMRC) which was used to raise awareness with 133 other patient charities. Patient forms are regularly distributed to patient organisations. Forms are also distributed nationally for patients via pharmacy bodies through campaign work, including static adverts and patient videos to raise the profile of the Scheme. In a second communications phase aimed at paediatrics there was a collaboration with the Royal College of Paediatrics and Child Health's Youth Advisory Panel to ensure messages were shared with paediatric related patient organisations and bodies. The MHRA has also worked with the INFACCT patient charity to produce a guideline about reporting suspected ADRs in pregnancy<sup>7</sup>. In addition, the MHRA has also worked with a patient HIV organisation and they now discuss side effects and also help patients to complete an ADR report if needed.

The MHRA also communicates to priority groups as necessary (e.g. the elderly, paediatric medicines, mental health, etc.), using low or no cost channels to distribute messages, e.g. working with media, charities, social media, etc. One such case study is described in Annex I – Valproate and risk of abnormal pregnancy outcomes.

The MHRA has five regional centres who also help to promote ADR reporting amongst patient organisations. They are tasked to collaborate with patient organisations with the aim of educating and encouraging suspected ADR reporting. Some of the specific disease organisations and charities that they work with include: DiabetesUK, Epilepsy Action, National Osteoporosis Society, British Lung Foundation, Breathe Easy, South Wales Ileostomy Group and Crossroads. Within devolved administration government areas the regional centres often work with Expert Patient Programmes locally. Regional centres also partner with local patient organisations to speak at congresses and conferences, supply leaflets and forms, and packs when required.

As a part of the main 50th anniversary event of the Yellow Card Scheme, all MHRA national patient stakeholders were identified and invited to attend to cover key therapeutic areas.

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<sup>7</sup> Retrieved from: <https://www.gov.uk/drug-safety-update/yellow-card-update-to-form>

MHRA has a specific Patient and Public Engagement team and Strategy team of two to three persons within the Communications team, who work with PV colleagues for campaign work to identify relevant patient organisations to engage with. The MHRA also has a specific Patient and Public Expert Advisory Group<sup>8</sup> consisting of 15 external members. Within their remit and specific to ADR reporting is their advice on ways to encourage patient reporting. This includes recognising the importance of the patient experience and giving advice on information provided to patient who reports ADRs. The MHRA also has a Patient Group Consultative Forum (PGCF), whose members have an interest in medicines and medical devices, which consists of over 70 individual members representing a wide range of different medical conditions, charitable organisations and patient and carer networks. The PV team works with both to encourage patient reporting.

Patient information leaflets have also helped to encourage reporting. The contribution is apparent from analysis of the Yellow Card website data field ‘where did you hear about us?’, which reporters are able to select when reporting. It shows a 152% (708 reports) increase in reporters selecting the ‘Patient Information Leaflet’ field in 2015.

Patients are now an established and growing reporter group within the Yellow Card Scheme. However, the MHRA acknowledges that there is still a lot of progress to be made in this area and it is committed to further strengthen patient reporting.

**Table 1 Number of UK spontaneous suspected ADR reports received directly from patients, carers and parents via the Yellow Card Scheme, which shows an increase of 228% in the last 5 years.**

Year	Number of UK spontaneous suspected ADR reports received directly from patients, carers and parents via the Yellow Card Scheme	Proportion of the total number of UK spontaneous suspected ADR reports
2011	1664	6%
2012	1829	7%
2013	2833	9%
2014	3805	12%
2015	5471	14%

<sup>8</sup> Retrieved from: <https://www.gov.uk/government/organizations/commission-on-human-medicines/about/membership#patient-and-public-engagement-eag>

## MHRA Recent case study: Valproate and of risk of abnormal pregnancy outcomes

In January 2015, a Drug Safety Update (DSU) article by the MHRA advised healthcare professionals that children exposed to valproate in utero are at high risk of developmental disorders and congenital malformations. The EU-agreed Risk Minimisation Materials were distributed with the letter and links to both were contained in the DSU article. In the subsequent 12 months the MHRA staff from PV and communications divisions worked collaboratively with the Marketing Authorisation Holder (MAH) concerned and, through major consultation with patient groups and professionals, produced a final communications toolkit, which was released on 8 February 2016. The toolkit consisted of: a patient card, a patient guide, a checklist and a booklet for healthcare professionals, as well as the carton labelling which the MAH are now rolling out globally.

The MHRA developed these new communication materials for utilisation by organisations and healthcare professionals to discuss risks and benefits with patients. Besides the MAH, the development of the materials involved continuous partnership through stakeholder group meetings, phone calls and written communications. The process also involved meetings of the senior members of the MHRA team with the Royal Colleges, voluntary organisations and the Minister to explore ways for professional bodies to support the messages. Several members of the Royal Colleges and voluntary groups from across various disciplines also attended stakeholder meeting with patients.

These new communication materials were published in the MHRA's February 2016 DSU: <https://www.gov.uk/drug-safety-update/valproate-and-of-risk-of-abnormal-pregnancy-outcomes-new-communication-materials>.

The following groups specifically support the release of the toolkit on their respective websites: Epilepsy Action, Epilepsy Research UK, Epilepsy Society, Young Epilepsy, Bipolar UK, FPA – the sexual health charity, Organisation for Anti-Convulsant Syndrome (OACS), INFACT, Migraine Action, FACS-Aware, the Royal College of Midwives and the Royal College of Pharmacists.

## **Annex 5. The SCOPE checklist for NCAs' consideration when engaging in collaboration with patient organisations**

### **I. General considerations**

- Consider including collaboration with patient organisations as a part of a strategic NCA document (please consider defining the aims and scope of the collaboration)
- Consider available NCA resources (i.e. human, financial) when engaging in collaboration with patient organisations
- Consider having dedicated personnel/contact points within the NCA for collaboration with patient organisation (e.g. personnel from PV, public relations, another department or a combination of the above).

### **II. Targeting/identifying patient organisations**

- Establish what would be the best possible way to have an overview of all the existing patient organisations in the MS, depending on the local situation
- Check if there is a national registry of patient organisations
- Identify 'umbrella' organisations
- Provide NCA contact information for the collaboration with patient organisations on NCA's webpage.

### **III. Eligibility of patient organisations**

- Internally discuss eligibility criteria:
- Does the mission/objectives of the patient organisation need to be defined and/or published?
- Does the patient organisation need to have a specific structure/are there specific requests for the patient organisation governing structure?
- Does the patient organisation need to have a specific interest in medicinal products?
- Disclosing of sources of funding (both public and private) to the NCA
- Disclosing of conflicts of interest to NCA.



#### **IV. Types of patient organisations**

- Decide if the NCA will collaborate with individual patient organisations and/or ‘umbrella’ organisations (based on the available resources and expertise in the NCA). You may reflect on the area in which the organisation is active, its maturity, influence, size, etc.
- Decide if the NCA will collaborate with disease-specific patient organisations.

#### **V. Establishing a collaboration**

- Consider a proactive approach (in the majority of cases)
- Define internal procedure if the NCA is approached by patient organisations
- Encourage continuous cooperation and collaboration on a case-by-case basis
- Establish if the NCA is approaching all patient organisations with the same objective or whether there are some specific objectives related to the type of patient organisation, which should be addressed differently.

#### **VI. Scope of collaboration/types of performed activities**

- Decide on the scope of collaboration:
- Promotion of patients’ ADR reporting
- Education on safety of medicines
- Financial support to patient organisations
- Other
- Consider what are the interests of patient organisations or public in general
- Consider involvement of patient organisations in regular NCA activities (e.g. involvement in scientific committees, input on educational materials aimed at patients, patient information leaflets or other NCA documents intended for the public).

#### **VII. Impact of collaboration**

- Consider the best way to measure the impact of collaboration with patient organisations on the national PV system, national healthcare system, NCA and patient organisations themselves, etc.

#### **VIII. Presentation of results and transparency**

- Consider the best way to present information on collaboration with patient organisations internally within the NCA
- Consider the best way to present information on collaboration with patient organisations to the interested public (e.g. publishing highlights on the NCA website).