SCOPE Stakeholder Event 20-21 March 2017, Table Discussion (1)	
Question 1: What can we do to further strengthen ADR reporting?	**Question 2: How can we improve getting relevant safety information to patients?**
Empower all people and build trust	Improve PILs and QRD template - use of medical terms (common, rare, very rare), include both benefit and harm information, summary boxes
Pay HCP's (like in Japan or Malta)	NCAs need a well-developed communications strategy
Targeted information sent to doctors prescribing certain drugs (high risk medicines)	Provide a dedicated phone service for medicines information
Assign ADR-managers in hospitals	Training of HCPs to handle patient queries
Public campaigns and events - TV, billboards, radio, newspapers, expand Take & Tell	Use digital technology to improve time and accessibility 1. Applications for patients - specific medicines and reporting apps should be integrated 2. QR codes 3. Replace paper with digital information
Promotion of reporting in waiting rooms at hospitals, clinics and pharmacies	Improve baseline public knowledge about safety information - face-to-face meetings, online learning modules (funding to facilitate training activities)
Advertising and dissemination of information through social media channels and technology (RSS feeds, emails)	Ensure websites are easier to navigate and interactive
Use of patients stories for websites, TV, campaigns, leaflets	Training of patient organisations to support patients
Availability of paper reporting forms in waiting rooms / pharmacies or iPads for e-reporting	Improve information provided - simple language
Offer easy IT tools for patients and HCPs to use for reporting e.g. apps	Be transparent with what data is used for, and results of studies
Integration of reporting systems with clinical systems, EHR	Ensure language used in all communication channels is fit for purpose & multi-lingual (simple native language)
Branding (Yellow Card in UK)	Use different formats of information - text, videos, infographics, audio, website quizzes

Better use of PV officers in patient organisations and officers in health institutions to disseminate information	Improve regulatory documents
Media (be more opened to general public)	Share post authorisation information
Add ADR section on patient organisation websites	Triangulate the link with patients, HCPs and industry (via regulators)
Improve quality of reports (by using e-learning and training tools)	Provide information in hospital / doctor waiting room
(Mandatory) training and education during all medical courses - HCPs and undergraduate student courses	Involve patients more - undertake focus groups, find out what patients would like
Integration of the SCOPE e-learning modules for training courses	Use industry to disseminate safety information to patients (aware of advertising difficulties)
Training of patient groups - a combined approach by both industry and regulators	Use of disease or drug registries - provide questionnaires/ information and link to reported outcomes
Education for the young - incorporate basic information about harms and benefits of medicines into school curriculums to catch patients early	Evaluate impact of different communication methods and channels in different countries
Availability of information applicable for different levels of ADR knowledge	Website information pop ups; "click here for the latest safety information"
Availability of a range of information sources - analogies, education games, leaflets, e-learning, videos	Enable tailoring / personalised information - patients should be able to select the illnesses/products of interest
Education for patients (to talk to HCPs about ADRs)	Publish patient stories - actions and outcomes; promote the importance of reporting
Translation of campaign/ ADR information into multiple languages	Public health campaigns targeting patients
Consider off label use reporting	Use of social media channels - Facebook, YouTube
Add information about ADR reporting to PIL and leaflets	Ensure product information (e.g. from all products with an active substance including generics) is accessible digitally
Add paper reporting form to medicine packs (insert inside or print form / web links on prescription bag)	User friendly education materials
Involvement of professional bodies, HCP societies in risk communications	Information from trusted sources - NCAs, national bodies, colleges, industry

PR concentrated on positive examples / experiences how reporting helped the patients/society	Influence google algorithms
Assure structured and informative feedback to reporter, what happened as a result of reporting, point to further information available	Allow local doctor/pharmacy to disseminate information to patients
Availability of both electronic and paper forms for those not comfortable with new technology	Share DHPC's with patients
Different approaches for different countries to suit healthcare system	Increased collaboration with patients organisations
	Target pharmacy staff to give key information for medicines regularly taken
	Engage patients early in the PV process (study design etc.)
	Feedback to patients & patient organisations on reporting
	Reminder of process behind ADR reports

SCOPE Stakeholder Event 20-21 March 2017, Table Discussion (2)	
Question 3: How we can enhance reaching healthcare professionals with timely safety information/advice?	**Question 4: How will SCOPE materials help to support consistent high standards in PV assessment capabilities/ benefit and harm assessment?**
Relevant safety alerts needed at the time of prescribing	Get SCOPE workflows into medical/pharmacy curriculums
Provide alerts through internet; safety newsletters sent electronically to anyone who prescribes medicines	Allow harmonisation
Need trustable sources (issue of trust with social media), certification of websites as trusted source for health information and reporting	Promote the E-learning modules and tools generated
Increase communication channels - not only DHCPs	Continuously update SCOPE materials (sustainability)
Use digital technology to improve time and accessibility 1. Applications for patients - specific medicines and reporting apps should be integrated 2. QR codes 3. Replace paper with digital information	Make materials and tools available and easily accessible
Connecting electronic databases with NCA safety information - improve information availability	Receive and take on board feedback and lessons learnt
Use standardised text in e-mail communication	SCOPE materials provide consistent guidance
Follow up via phone to check if important communication was received by HCPs (confirmation)	Sharing best practices and knowledge through all MS
Focusing on patients taking different types of medications	Development of EU platform with information about PV for patients and HCP
Unify reporting systems in Europe and globally	One standard for regulators and transparency to industry
Training people in nursing homes and carers on ADR reporting and vigilance	Ensure correct language is used
Bigger emphasis on pharmacists informing patients about risks associated with a medicine	Materials will help less mature/experienced Member States in implementation

Focus on complex treatments, complementary therapies/ medicines other medications not prescribed by HCPs	Use LinkedIn for contacts and advertising of materials
Increased visibility of the regulators to the general public	Monitoring the efficacy of authorised products - better use of real life data, SCOPE has not fully explored this
Improve reputation of pharmaceutical industry	Training sessions
Early engagement with HCPs regarding benefit-risks and aims of a product	Have a helpdesk for questions on implementation or other challenges faced
Use NCA's to disseminate information	Promote materials to patients and embed reporting positivity and confidence
Better SPCs regulatory documents	Keep the source trustworthy
Measure the impact of different communication channels and tools in each country	Exchange PV programs in a range of areas; assessment, communications etc.
Reduce duplication between agency and regulators - consistency and collaboration	Follow through on actions from the SCOPE reports
A pop up alert to show when prescribing a medicine, informing of any updates which can be read to patients	Advertise / publicise the SCOPE deliverables suitable for target groups (HCP module)
Alerts identifying new information e.g. new contraindication	NCAs must embed the training materials; new staff must complete the relevant modules
HCPs to tell patients to read the PIL	Collaboration and initiatives with patient organisations and industry
Incentivise HCPs	Regular meetings to be held by NCAs; scientific advice and public hearings
Construct a platform to tackle this initiative with a coordinated and cost effective approach	Continue publicising materials at DIA and prominent conferences
DHPCs - collaboration with NCA and industry to combine information	Conclusions to be taken on board by Health Authorities/ Ministries of health
Use of bar codes more various challenges	Give working parties achievable goals and review progress at meetings
Use of electronics at point of care and prescribing	SCOPE materials bridge the gap between industry and NCAs and provide insight into the regulatory world

Reporting for prescribing and dispensing systems should be mandated at EC level	NCAs trained to the same level - needs to be accredited across EU for regulators
Point of care alerts to doctors, pharmacies integrated into their prescription systems	Increased feedback, dialogue and scientific advice meetings
Include PV chapter in guidelines and recommendations	Consistent training and cooperation within the network of assessors
Education in Universities	Monitoring the use/application of SCOPE deliverables
Implement DHCPs in health care systems, recognisable mark for safety information approved by regulatory agencies	More involvement of patients organisation e.g. help with translations into lay language
Academic detailing - public funded information campaigns where public doctors and pharmacists meet with GP's (1:1 information meetings)	Translation of materials to all European languages
Better data integration - providing data in easy formats (instead of developing more material)	E-Learning - good practices from each Member State
	Preference for higher level guidance for industry rather than detailed GVP
	Close gap between quality of life versus ADR expectation setting for patients and HCP
	Provide clarity with terminology - seriousness, severe, impact
	User testing of information - level of knowledge assessment
	Bring SCOPE deliverables to life with real-life examples
	Empower patients