



## Standard operating procedure

Title: Assessment of competing interests of Agency employees		
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### 1. Purpose

To describe the procedure for assessing competing interest of Agency employees.

The Decisions of check for competing interests described in this SOP are applicable to Agency employees in categories A, B and Y.

The Decisions of check for competing interests described in this SOP are not required for Agency employees in categories C and Z.

<b>A:</b> Executive Director; Deputy Executive Director; Senior Medical Officer; scientific and regulatory managers
<b>B:</b> Scientific, regulatory and other administrators involved in product-specific activities
<b>C:</b> Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non product-specific activities
<b>Y:</b> Executive Director; Deputy Executive Director; non-scientific/regulatory managers and administrators
<b>Z:</b> Non-scientific/regulatory assistants

See Annex 3 for further categorisation details.

### 2. Scope

This SOP applies to all reporting officers across the Agency.



### 3. Responsibilities

It is the responsibility of the Executive Director and each Head of Division, Department, Function, Service and Office to ensure that this procedure is adhered to within their own Division, Function, Department, Service and Office. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of Section 9.

### 4. Changes since last revision

Extensive revision to rewrite SOP.

### 5. Documents needed for this SOP

- Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment (located at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2016/11/WC500216191.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216191.pdf)).
- Annex 1: Determining involvement in Agency activities in case of interests declared in a pharmaceutical company.
- Annex 2: Determining involvement in Agency activities in relation to staff members with administrative or technical duties in case of declared personal interests other than interest in a pharmaceutical company.
- Annex 3: Categorisation of EMA staff.
- Template 1: Decision of checks for competing interests for category A role (available in SAP).
- Template 2: Decision of checks for competing interests for category B role (available in SAP).
- Template 3: Decision of checks for competing interests for category Y role (available in SAP).
- Staff Declarations of interest form (available in SAP).

### 6. Related documents

- Decision on rules concerning the handling of declared interests of national experts on secondment, visiting experts, trainees and interims of the European Medicines Agency (available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2012/02/WC500122907.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500122907.pdf) )
- Declaration of interests database user guide (for managers) (available at [http://emeaplus/EMEAPlus\\_WebsiteNew/HR/html/Ethics\\_DoI.htm](http://emeaplus/EMEAPlus_WebsiteNew/HR/html/Ethics_DoI.htm) )
- SOP/EMA/0044 on requesting and recording exceptions

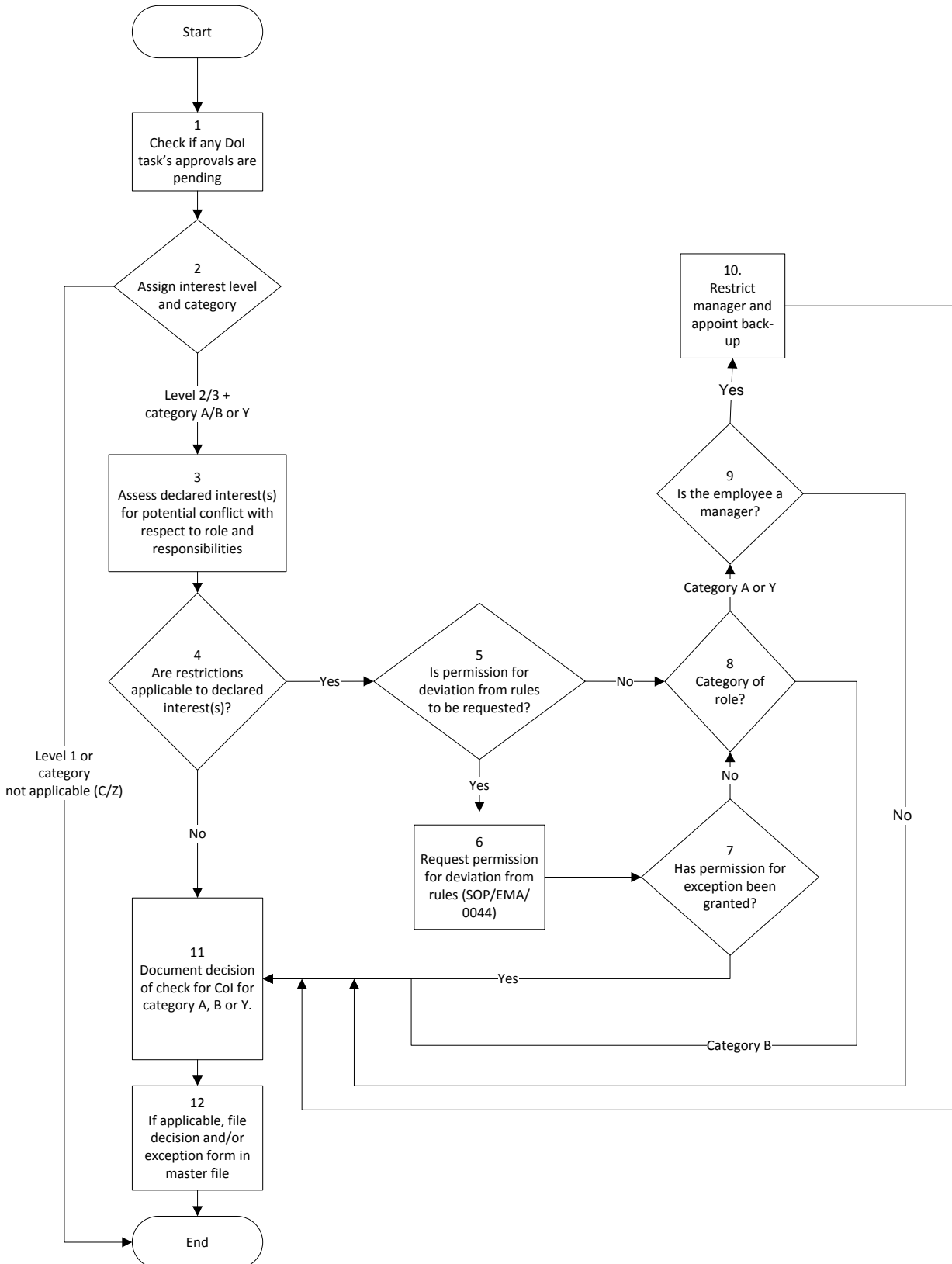
### 7. Definitions

A-SG-QRM:	Quality assurance, Risk Management and ex-post control coordination function
DoI:	Declaration of interests
DREAM:	Document records electronic archive management
Employee:	Temporary agent, contract agent, national expert on secondment, visiting expert, interim or trainee (contractors are excluded from this definition)

Manager: Executive Director, Deputy Executive Director, Senior Medical Officer, Head of Division, Department, Function, Service and Office, including deputy managers and acting managers

Reporting officer: Executive Director and Head of Division, Department, Function, Service and Office including deputy managers and acting managers charged with preparation of the performance evaluation report of the manager or employee

### 8. Process map(s)/ flow chart(s)



## 9. Procedure

### Notes

- Checks for competing interests are conducted at least once a year when the annual DoIs of employees are assessed and an interest level is assigned by the reporting officer.
- On completion of a spontaneous or annual declaration of interests by a staff member, the reporting officer shall reassess the declared interests and, in the event of any changes, reassign the staff member to a different interest level.
- An employee who changes his duties within the Agency is required to verify the need to update his declaration of interests. On receipt of an updated declaration of interests, the new reporting officer shall assess and, if necessary, reassign the staff member to a different interest level.
- The reporting officer shall document the decision of the check of competing interests and the reason for assigning staff member responsibilities related to a specific medicinal product, where applicable in the case of category A and B role.
- The reporting officer shall document the decision of the check of competing interests and the reason for assigning a staff member to the specific procedure or duty, where applicable, in the case of category Y role.
- Documented checks are not required when assigning a back-up for short-term absence (e.g. missions, vacation leave, sick leave).
- When a Manager is to undertake a role listed as category B or Y in the Annex 1 and 2, the check for competing interests must be conducted independently by his/her reporting officer.

Step	Action	Responsibility
1.	<p>Check if any DoI tasks' approvals are pending in the Manager's approval section in SAP (refer to managers' user guide).</p> <p><i>Note:</i></p> <p><i>If the employee did not declare any interests, interest level 1 is automatically assigned to the DoI and it will not appear in the approval section in SAP as no action is required.</i></p>	Reporting officer
2.	<p>If the interest level has not yet been determined on the basis of the most recent annual/updated valid DoI in SAP, assess declaration and assign interest level – interest level 1, interest level 2 or interest level 3 - in SAP (refer to managers' user guide). In addition, assign a decision type: category A, category B, category Y or not applicable.</p> <p>If the interest level is 1 (i.e. no declared direct or indirect interests or interests in a governing body), a decision of check for potential competing interests is not required. End of procedure.</p> <p>If the interest level is 2 (i.e. declared indirect interests: close family member, principal investigator, investigator) or 3 (i.e. declared direct interests: employment, consultancy, strategic advisory role) but the decision type is category not applicable (role</p>	Reporting officer

Step	Action	Responsibility
	<p>C or role Z), a decision of check for potential competing interests is not required. End of procedure.</p> <p>If the interest level is 2 (i.e. declared indirect interests: close family member, principal investigator, investigator) or 3 (i.e. declared direct interests: employment, consultancy, strategic advisory role) and the decision type is category A, B or Y, go to step 3.</p> <p><i>Notes:</i></p> <ul style="list-style-type: none"> <li>• <i>Category A includes Executive Director, Deputy Executive Director, Senior Medical Officer, scientific and regulatory managers.</i></li> <li>• <i>Category B includes scientific, regulatory and other administrators involved in product-specific activities</i></li> <li>• <i>Category C includes scientific/regulatory assistants, scientific, regulatory and other administrators involved in non product-specific activities</i></li> <li>• <i>Category Y includes non-scientific/regulatory managers and administrators.</i></li> <li>• <i>Category Z includes Non-scientific/regulatory assistants</i></li> </ul>	
3.	<p>Check and assess whether interests declared by the employee in the most recent annual/updated valid DoI (available in SAP; refer to managers' user guide) present a potential conflict:</p> <ul style="list-style-type: none"> <li>• With respect to the staff member's involvement in scientific or regulatory duties, for category A and B roles.</li> <li>• With respect to the staff member's involvement in administrative or technical (non-scientific) duties, for category Y.</li> </ul> <p>Involvement in the Agency activities is determined by taking into account:</p> <ul style="list-style-type: none"> <li>– the nature of the declared interest,</li> <li>– the timeframe during which such interest occurred,</li> <li>– the staff member's specific role and responsibilities</li> </ul> <p>For further details, refer to the Decision on Rules for Staff.</p>	Reporting officer
4.	<p>If no restrictions apply to the declared interest(s), go to step 11</p> <p>If restrictions apply to the declared interest(s), go to step 5.</p>	Reporting officer
5.	<p>If permission to deviate from the Decisions on rules is to be requested, go to step 6.</p> <p>If no deviation from the Decisions on rules is to be requested, go to step 8.</p>	Reporting officer

Step	Action	Responsibility
	<i>Note: Permission to deviate from the Decisions on rules may be requested if there are exceptional circumstances that preclude you from assigning a medicinal product or a role to another employee.</i>	
6.	<p>Request the Executive Director's permission to deviate from the Decisions on rules in order to assign a medicinal product or role to the employee (refer to SOP/EMA/0044).</p> <p>Provide a justification in the request for exception based on the general principles for determining involvement in activities detailed in the Decisions on rules. When applicable, consult the Head of Department before referring the request form to the Head of Division.</p>	Reporting officer
7.	<p>If permission for an exception is not granted by the Executive Director, go to step 8.</p> <p>If permission for an exception has been granted by the Executive Director, go to step 11.</p>	Reporting officer
8.	<p>If category A or Y was assigned, go to step 9.</p> <p>If category B was assigned, go to step 11.</p>	Reporting officer
9.	<p>If employee <u>is not</u> a manager and category Y was assigned, go to step 11.</p> <p>If employee is a manager and was assigned category Y or A, go to step 10.</p>	Reporting officer
10.	<p>Restrict the manager for the medicinal product or company and appoint a back-up.</p> <ul style="list-style-type: none"> <li>• The scientific/regulatory manager (category A) is instructed not to undertake any duties and responsibilities in relation to the declared medicinal product(s) or medicinal products from the declared company (ies). These duties and responsibilities are delegated to his/her back-up.</li> <li>• The non-scientific/regulatory manager (category Y) is instructed not to undertake any duties and responsibilities in relation to the declared company (ies). These duties and responsibilities are delegated to his/her back-up.</li> </ul> <p>Continue with step 11.</p>	Reporting officer
11.	<p>Document decision of check for competing interest for category A, B and Y. (see notes below; refer to managers' user guide for instructions on completing an electronic form in SAP).</p> <p>For a category B:</p> <ul style="list-style-type: none"> <li>• if no restrictions apply (i.e. if proceeding from step 4), select option 1;</li> <li>• if an exception has been granted (i.e. if proceeding from step</li> </ul>	Reporting officer

Step	Action	Responsibility
	<p>7), select option 2.</p> <p>For a category A and Y:</p> <ul style="list-style-type: none"> <li>• if no restrictions apply (i.e. if proceeding from step 4), select option 1</li> <li>• if restrictions are applied (i.e. if proceeding from step 10), select option 2</li> <li>• if an exception has been granted (i.e. if proceeding from step 7), selection option 3.</li> </ul> <p>If an exception has been granted, attach a scanned PDF file to the decision of check in SAP (refer to managers' user guide). Alternatively, attach a photocopy of the request for exception form to the decision, if an MS Word or customised template is being used (see notes below).</p> <p><i>Notes:</i></p> <ul style="list-style-type: none"> <li>• <i>Decision of check for competing interests documents must be completed electronically in SAP by the reporting officer in order to ensure that a permanent auditable record is available. A version in MS Word must only be used when SAP cannot be accessed. In case of a granted exception, attach a photocopy of the request for exception form to the decision of check form.</i></li> <li>• <i>The database generates automated e-mail messages to notify the reporting officer and/or the manager/employee when an electronic form is passed on from one user to another within the workflow.</i></li> </ul>	
12.	If applicable, A-SG-QRM register the paper version of decision of check document and/or original request for exception form" and the file the original request.	Reporting officer

## 10. Records

Completed decisions of check for competing interests are retained electronically in SAP.

## Annex 1

Summary of the restrictions that are applied to staff members for declared interests in a pharmaceutical company based on their roles and responsibilities.

Declared interests in a pharmaceutical company		Involvement of staff members in scientific or regulatory duties			Involvement of staff members in administrative or technical (non-scientific) duties	
Declared interest	Time since declared interest ended (in years)	A	B	C	Y	Z
Employee (executive role or lead role in development of medicinal product)	Current interest	X	X	X	X	X
	0 to 3	XC/XP	XC	F	F	F
	3 to 5	XC/XP	F	F	F	F
Employee (cross company role other than executive role, or medicinal product involvement other than lead role in development of medicinal product)	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Consultancy to company	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Strategic advisory role for company	Current interest	X	X	X	X	X
	0 to 3	XC	XC	F	F	F
Financial Interests	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Principal investigator	Current interest	X	X	X	X	X
	0 to 3	XP	XP	F	F	F
Investigator	Current interest	X	X	X	X	X
	0 to 3	XP	XP	F	F	F
Grant/other funding to organisation/institution	Current interest	X	X	X	X	X
	0 to 3	F	F	F	F	F
Close family member	Current interest	XC	XC	F	F	F
	0 to 3	F	F	F	F	F

**A:** Executive Director; Deputy Executive Director; Senior Medical Officer; scientific and regulatory managers

**B:** Scientific, regulatory and other administrators involved in product-specific activities

**C:** Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non product-specific activities

**Y:** Executive Director; Deputy Executive Director; non-scientific/regulatory managers and administrators

**Z:** Non-scientific/regulatory assistants

Outcome restriction level	Impact of the outcome
X	No involvement in activity allowed.
XC	No involvement with respect to medicinal products from the relevant company.
XC/XP	No involvement with respect to either medicinal products from the relevant company (XC) or in procedures involving the relevant medicinal product (XP).
XP	No involvement with respect to procedures involving the relevant medicinal product.
F	Full involvement in activity allowed.



## Annex 2

Summary of the restrictions that are applied in relation to staff members with administrative or technical duties in case of declared personal interests, other than interests in a pharmaceutical company.

Declared personal interests, other than interests in a pharmaceutical company		Involvement of staff members in scientific or regulatory duties			Involvement of staff members in administrative or technical (non-scientific) duties	
Declared interest	Time since declared interest ended (in years)	A	B	C	Y	Z
Employment, consultancy or strategic advisory role in other entities possibly providing services to the EMA (e.g. IT, facilities, administration, catering)	Current interest	n/a	n/a	n/a	X	X
	0 to 3	n/a	n/a	n/a	XC-nPhC	F
Financial interest in other entities possibly providing services to the EMA (e.g. IT, facilities, administration, catering)	Current interest	n/a	n/a	n/a	X	X
	0 to 3	n/a	n/a	n/a	F	F
Close family member	Current interest	n/a	n/a	n/a	XC-nPhC	F
	0 to 3	n/a	n/a	n/a	F	F

**A:** Executive Director; Deputy Executive Director; Senior Medical Officer; scientific and regulatory managers

**B:** Scientific, regulatory and other administrators involved in product-specific activities

**C:** Scientific/regulatory assistants; scientific, regulatory and other administrators involved in non product-specific activities

**Y:** Executive Director; Deputy Executive Director; non-scientific/regulatory managers and administrators

**Z:** Non-scientific/regulatory assistants

Outcome restriction level	Impact of the outcome
n/a	Not applicable.
X	No involvement in activity allowed.
XC-nPhC	No involvement with respect to duties involving the relevant company (non-pharmaceutical).
F	Full involvement in activity allowed.

# Annex 3

## Categorisation of EMA staff

A	B	C	Y	Z
ED (Executive Director)	D-DS-OME	P-CI-SCS	ED (Executive Director)	Assistants (I-Div + A-Div + AF-PB + AF-AUD)
DED (Deputy Executive Director )	D-DS-PME	D-SD-WPS	DED (Deputy Executive Director )	
All Heads of Division in D,E,P,V,S	D-DS-SCA	S-PH	I-Division (managers and administrators in I Division)	
Head of Division in AF-SI	E-PM	Assistants (V-Div + D-Div + E-Div + P-Div)	A-Division (managers and administrators in A Division)	
All Heads of Department in D,E,P,V,S Divisions	E-SR	DED-ILO	AF-PB (manager and administrators)	
Head of Department in AF-LD	V-VM	AF-INT	AF-AUD (manager and administrators)	
All Heads of Service in D,E,P,V,S Divisions	E-SR-REA	DED-MBN		
Heads of Office in D,E,P,V,S Divisions	AF-LD	I-BD-BUS		
Heads of Office in AF-LD-LTO AF-LD-AFO AF-LD-SPO AF-SI-OSR AF-SI-SCC AF-INT DED-MBN DED-PCM DED-ILO DED-DAP	P-PE	S-CO-OLD		
	P-CI-MQC	ED-EXO		
	P-CI-CNC			
	P-CI-PDC			
	S-CO			
	D-SD-QME			
	D-SD-BMS			
	D-SD-CPN			
	DED-DAP			
	DED-PCM			
S-SC-SME				
Head of AF-SMO				

A-Division: Administration and Corporate Management Division  
AF-AUD: Audit Office  
AF-INT: International Affairs  
AF-LD: Law Department  
AF-LD-AFO: Anti-Fraud Office  
AF-LD-LTO: Litigation Office  
AF-LD-SPO: Long Term and Special Projects Office  
AF-SI: Scientific Committees Regulatory Science Strategy Department  
AF-SI-SCC: Scientific Committees Coordination Office  
AF-SI-OSR: Regulatory Science Observatory Office  
AF-PB: Portfolio Board Department  
AF-SMO: Senior Medical Officer  
CoI: Competing interest  
DED: Deputy Executive Director  
DED-DAP: Document Access and Publication Office  
DED-ILO: EU Institutional Liaison Office  
DED-MBN: Management Board and HMA Office  
DED-PCM: Policy and Crisis Management Office  
ED: Executive Director  
ED-EXO: Office of the Executive Director  
D-Division: Head of Human Medicines Research & Development Support Division  
D-DS-OME: Orphan Medicines Office  
D-DS-PME: Paediatric Medicines Office  
D-DS-SCA: Scientific Advice Office  
D-DS-SIS: Scientific Support and Innovation Office  
D-SD-BMS: Biostatistics and Methodology Support  
D-SD-CPN: Clinical Pharmacology & Non-Clinical Support  
D-SD-QME: Quality Office  
DoI: Declaration of interests  
DREAM: Document records electronic archive management  
E-Division: Human Medicines Evaluation Division  
E-PM: Procedure Management Department

E-SR: Scientific and Regulatory Management Department  
I-Division: Information Management Division  
I-BD-BUS: Product & Application Business Support Office  
P-Division: Inspections, Human Medicines Pharmacovigilance & Committees Division  
P-CI-CNC: Clinical & Non-Clinical Compliance Office  
P-CI-EDM: Experts and Declarations of Interests management  
P-CI-PDC: Parallel Distribution & Certificate Office  
P-CI-MQC: Manufacturing & Quality Compliance Office  
P-CI-SCS: Scientific Committees Secretariat  
S-Division: Stakeholders & Communication Division  
S-CO: Communication Department  
S-CO-OLD: Online & Corporate Design Office  
S-SC: Corporate Stakeholders Department  
S-SC-SME: SME Office  
S-PH: Public Engagement Department  
V-Division: Veterinary Medicines Division  
V-VM: Veterinary Medicines Department