WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

federal agency for medicines and health products


# Medicines, Public Health and the Media
# Brussels – November 18 2014

## Scientific Institute of Public Health

### Section of Medicines Control (OMCL)

Operational Directory:
Food, Medicines and Consumer Safety

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Belgian Chairmanship
Présidence belge

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# The Health Authorities in Belgium

**MINISTER OF SOCIAL AFFAIRS AND PUBLIC HEALTH**
**MINISTER OF ENVIRONMENT**

| Preparation of Policy | Scientific Research as support to Policy | Control & Inspection |
|---|---|---|
| FPS Health, Food Chain Security and Environment | Scientific Policy<br><br>WIV-ISP<br>VAR<br><br>Superior Health Council | Federal Agency for the Food Chain Security<br><br>Federal Agency for Medicines and Health Products |

WIV-ISP : Scientific Institute of Public Health
VAR : Veterinary and Agrochemical Research Centre
KCE : Belgian Health Care Knowledge Centre

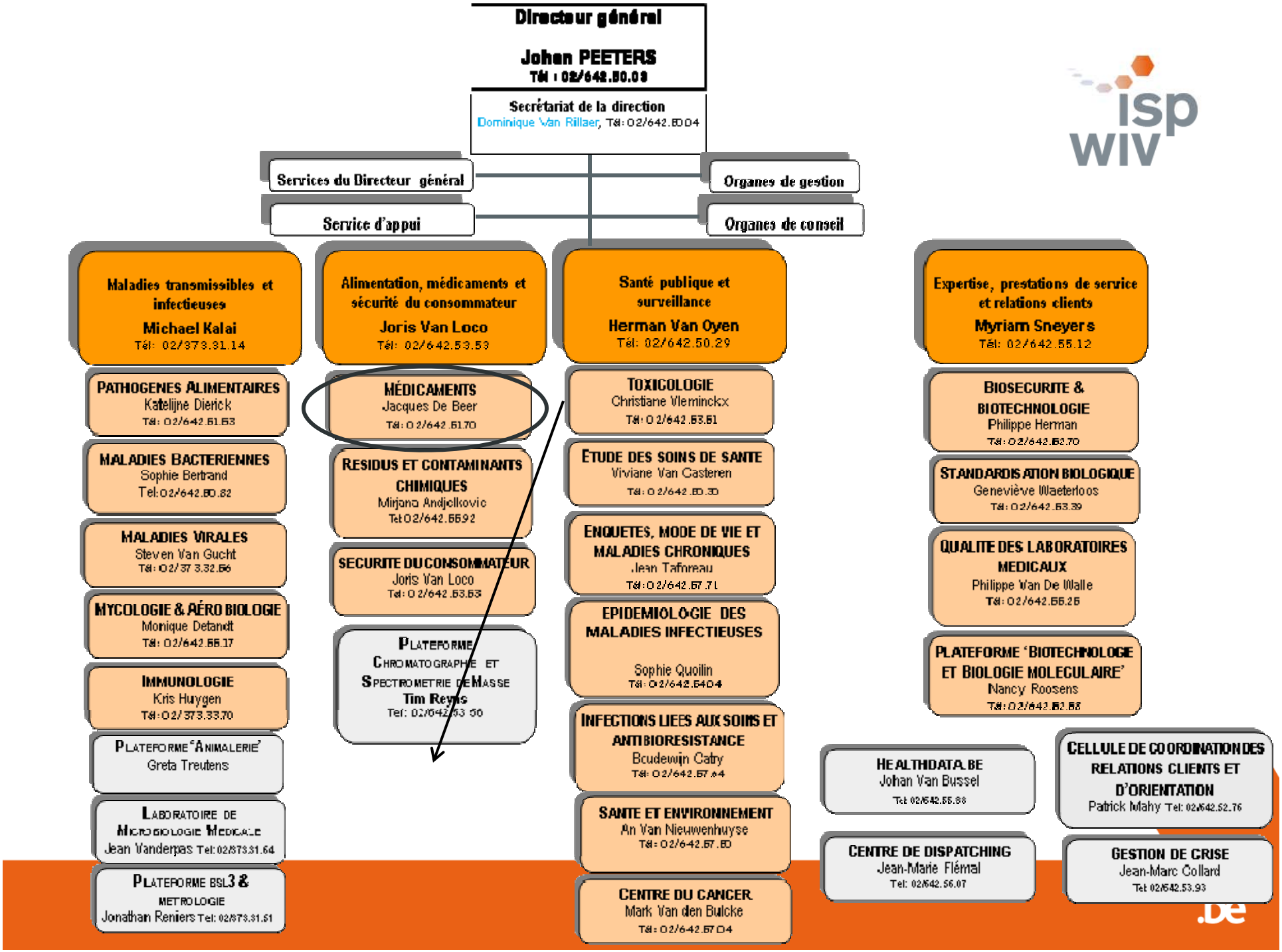
# Mission
# Science at the service of Public health, Food chain Safety and Environment

The Scientific Institute of Public Health (WIV-ISP) supports health policy through scientific research, and by providing expert advice and scientific services to different professional stakeholders (e.g. GPs).

We formulate science-based recommendations and solutions for a proactive health policy on the national and different international levels.

We monitor the health status of the Belgian population and the related health indicators using state-of-the-art expert methodology, which is developed, evaluated and applied within the boundaries of a validated quality assurance framework.

We develop advanced solutions to diagnose, prevent, and treat endemic and emerging diseases, as well as solutions that enable the identification and prevention of other health risks, including the environmental risks.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# Duties of the Medicine Control Service in relationship to the Mission Declaration of the **Scientific Institute of Public Health**.

*To implement at the level of the Medicine Control Service the **strategic and operational aims and objectives** established in the defined **management and policy plan** developed by the General Director of the Scientific Institute of Public Health on behalf of the Minister of Public Health*

## *CORE ACTIVITIES of the Medicines Control section :*

1. Duties and assignments as ***"reference laboratory" by order of*** the *Federal Agency for Medicines and Health Products* (FAMHP).

2. Duties and responsibilities as ***OMCL*** ("Official Medicine Control Laboratory")

3. Research & Development: ***PhD research projects*** (external or internal grants (4 years) in ***collaboration with universities***

4. Occasional analysis projects asked by the FASFC (***identification of illegal preparations, herbs, food complements***), DG4 (***illegal cosmetics***), Ministry of the Interior: Blue Diamond (stability testing of ***oseltamivir*** tablets), DG5 (***damascenone in e-cigarets***)

## 1. External scientific service related activities

### a. Correct realisation and performance of the established contract with the FAMHP as most important stakeholder:

- Performing *conformity analyses* of sampled medicines according to a *plannified risk based sampling program* and according to the *ISO-17025 applied QA systeem*

- Continuous *maintenance* and *improvement* of the *QA system* (internal audits, BELAC audit, MJA by EDQM, participation in *proficiency testings* as e.g. *PTS*, *SUP*, *COSPTS*, *FAPAS*, …)

- Permanent *development of the scope of analysis* in relationship to *quality controle activities of new medicines* (bio-tech, bio-active peptides and proteins, illegal drugs and counterfeits) by means of *state-of-the-art* analytical techniques (Raman-spectroscopy and -microscopy, LC-NMR-spectroscopy, LC-ETD-ion trap-MS TOF en Q-TOF massaspectrometrie,..)

## a. *Correct realization and performance of the established contract with the FAMHP as most important stakeholder (continued):*

- Active participation in *trimestral consultation meetings* together with the *FAMHP* concerning the contract compliance.
- Active participation in *sampling planning meetings* together with FAMHP inspectors.
- Technical support during *QC laboratory inspections*.
- Active contribution in the *development and validation* of methods of analysis for *Therapeutic Magistral Formularium* preparations.
- Membership of *several Commissions* (Derogation Commission, Pharmacopoeial Subcommissions, …)

## *b. Assure active participation and involvement to the GEON netwerk activities (General OMCL Network) organised by EDQM*

- *"Counterfeit" working group* + communication of counterfeit product information
- *"Small Scale Preparations"* working group
- Quality Monitoring of *Stockpiled medicines* (working group)
- *CAP* (central authorized products) sampling and testing programme
- Participation in collaborative analytal performances for *Ph.Eur. CRS certifications*
- Active participation in *annual OMCL meetings*

## *b. Assure active participation and involvement in the GEON network activities (General OMCL Network) organised by EDQM (continued):*

- To be audited in a MJA to receive the quality attestation according to the *OMCL Network Quality Management System* (2009 – 2014 and 2014 – 2017)
- Participation in *Proficiency Testing Scheme* (PTS)
- *Market Surveillance Studies* (MSS)
- Participating as *technical auditor in MJAs* of other OMCLs
- Recently: participation in coordinated activities within the "***Official Cosmetics Control Laboratory***" network *(OCCL - EDQM)* and the ***Platform of European Market Surveillance Authorities in Cosmetics*** *(PEMSAC)* ( e.g.: development and validation of new cosmetics analysis methods)

## *c. Correct realization and performance of the analysis requests from the Federal Agency for Safety of the Food Chain (FASFC) concerning unknown illegal preparations (veterinary, raw materials, herbs, supplements):*

- Acquisition of the *BELAC accreditation* for the analysis of *illegal and unknown preparations* by means of ion-trap LC-(ETD) MS and single quad GC-MS

- Further development and extension of *mass spectra libraries* of new APIs and illegal substances and drugs, necesseray for identification.

- Correct *reporting of the analysis results* found.

## d. *Correct realisation and performance of the analysis requests programmed by DG4 concerning the control of illegal cosmetics:*

- Participation in and/or follow up of *meetings with DG4* about control *analysis of cosmetics* to be performed

- *Method development* and *–validation* for methods of analysis of *new toxic components* (allergens, hair dyes, teeth and skin bleaching substances, diethylene glycol, preservatives, …) in *cosmetics*,

- Application of the *new European legislation* on cosmetics (11 July 2013) concerning the presence of prohibited components

## e. *Analyses concerning stockpiled medicines in order of the Ministry of the Interior*

- *Stability testing* study of *Oseltamivir tablets* (cfr. KI-tablets in the past)

# “Peer reviewed” publications in the field of counterfeits en (illegal) medicines:

Comparison and combination of spectroscopic techniques for the detection of counterfeit medicines.
J. Pharm. Biomed. Anal., 53, 445-453 (2010)
Sacré P-Y, Deconinck E, De Beer T, Courselle P, Vancauwenberghe R, Chiap P, Crommen J, De Beer J,

A fast Ultra High Pressure Liquid Chromatographic method for qualification and quantification of pharmaceutical combination preparation of NSAID and antihistaminics.
J. Pharm. Biomed. Anal., 56, 200-209 (2011)
Deconinck E, Sacré P-Y, Baudewyns S, Courselle P, De Beer J.

Development and validation of a UHPLC-UV method for the detection and quantification of erectile dysfunction drugs and some of their analogues found in counterfeit medicines.
Journal of Chromatography A, 1218, 6439-6447 (2011)
Sacré P-Y, Deconinck E, Chiap P, Crommen J, Mansion F, Rozet E, Courselle P, De Beer J.

Detection of counterfeit Viagra® by Raman Microspectroscopy imaging and multivariate analysis.
J. Pharm. Biomed. Anal., 56, 454-461(2011)
Sacré P-Y, Deconinck E, Saerens L, De Beer T, Courselle P, Vancauwenberghe R, Chiap P, Crommen J, De Beer J.

Impurity fingerprints for the identification of counterfeit medicines - a feasibility study.
Anal. Chim. Acta, 701, 224-231, (2011)
Sacré P-Y, Deconinck E, Daszykowski M, Courselle P, Vancauwenberghe R, Chiap P, Crommen J, De Beer J.

Classification trees based on infrared spectroscopic data to discriminate between genuine and counterfeit medicines.
J. Pharm. Biomed. Anal., 57, 68-75 (2012),
Deconinck E, Sacré P-Y, Coomans D, De Beer J.

# “Peer reviewed” publications in the field of counterfeits en (illegal) medicines (continued):

A validated Ultra High Pressure Liquid chromatographic method for qualification and quantification of folic acid in pharmaceutical preparations.
J. Pharm. Biomed. Anal., 54, 995-1000 (2011)
E. Deconinck, S. Crevits, P. Baten, P. Courselle, J. De Beer

A validated Ultra High Pressure Liquid Chromatographic method for the characterisation of confiscated illegal slimming products containing anorexics.
J. Pharm. Biomed. Anal., 59, 38-43 (2012)
E. Deconinck, K. Verlinde, P. Courselle, J.O. De Beer

The quality coefficient as performance assessment parameter of straight line calibration curves in relationship to the number of calibration points.
Accreditation and Quality Assurance, 17, 265-274 (2012)
Jacques O. De Beer, Caroline Naert, Eric Deconinck

A validated GC-MS method for the determination and quantification of residual solvents in counterfeit tablets and capsules
J. Pharm. Biomed. Anal., 70,64-70 (2012)
E. Deconinck, M. Canfyn, P.-Y. Sacré, S. Baudewyns, P. Courselle, J.O. De Beer

Determination of benzene in different food matrixes by distillation and isotope dilution HS-GC/MS
Anal.Chim.Acta, 672 (1-2), 124-129 (2010)
Medeiros Vinci R., Canfyn M., De Meulenaer B., De Schaetzen T, Van Overmeire I, De Beer J., Van Loco J.

# “Peer reviewed” publications in the field of counterfeits en (illegal) medicines (continued):

A strategy for the identification of plants in illegal pharmaceutical preparations and food supplements using chromatographic fingerprints
Anal. Bioanal. Chem., 405, 2341-2352 (2013)
E. Deconinck, C. De Leersnijder, D. Custers, P. Courselle and J.O. De Beer

Accuracy profiles assessing the validity for routine use of HPTLC assays or drug formulations
J. Chromatogr.A, 1293, 159-169 (2013)
D.H. Shewiyo, E. Kaale, P.G. Risha, B. Dejaegher, J. De Beer, J. Smeyers-Verbeke and Y. Vander Heyden

Development and validation of a fast chromatographic method for screening and quantification of legal and illegal whitening agents
J. Pharm.Biomed.Anal., 83, 82-88 (2013)
B. Desmedt, V. Rogiers, P. Courselle, J.O. De Beer, K. De Paepe and E.Deconinck*

Chromatography in the detection and characterization of illegal pharmaceutical preparations
J. Chromatogr.Sci., 51, 791-806 (2013)
Eric Deconinck, Pierre-Yves Sacré, Patricia Courselle and Jacques O. De Beer

Evaluation of the residual solvent content of counterfeit tablets and capsules
J. Pharm. Biomed. Anal. 81-82, 80-88 (2013)
E. Deconinck, M. Canfyn, P.-Y. Sacré, P. Courselle and J.O. De Beer

# “Peer reviewed” publications in the field of counterfeits en (illegal) medicines (continued):

“Chemometrics and chromatographic fingerprints to discriminate and classify counterfeit medicines containing PDE-5 inhibitors”
E. Deconinck, P.-Y. Sacré, P. Courselle, J.O. De Beer
Talanta (2012) 100 123-133

“Characterisation of suspected illegal skin whitening cosmetics”
B. Desmedt, E. Van Hoeck, V. Rogiers, J.O. De Beer, K. De Paepe, E. Deconinck
Journal of Pharmaceutical and Biomedical Analysis 90 (2014) 85-91

“Headspace-gas chromatographic fingerprints to discriminate and classify counterfeit medicines”
D. Custers, M. Canfyn, P. Courselle, J.O. De Beer, S. Apers, E. Deconinck
Talanta 123 (2014) 78-88

“Evaluation of bioequivalence of counterfeit medicines of PDE-5 inhibitors”
E. Deconinck, S. Andriessens, J.L. Bothy, P. Courselle, J.O. De Beer
*Accepted for publication in* Journal of Pharmaceutical Analysis

# Vulgarising and press articles

Illegale huidblekende cosmetica op de Belgische markt
B. Desmedt, K. De Paepe, P. Courselle, J. O. De Beer, V. Rogiers and E. Deconinck.
SKIN (februari 2013)

Valse geneesmiddelen opsporen. Een nieuwe chemische analyse kan valse Viagrapillen van echte onderscheiden
(over het onderzoek op counterfeits van de dienst Geneesmiddelen).
(Knack 3 oktober 2012)

De Standaard: “Valse Viagra wordt steeds beter” (DS vrijdag 22 juli 2012) (over het onderzoek binnen de dienst Geneesmiddelen).

Activiteitenverslag WIV-ISP 2007-2008:
“Namaak van geneesmiddelen heeft gevolgen voor de patiënten, de zorgverstrekkers, de geneesmiddelenproducenten en het gezondheidsbeleid.” – Patricia Courselle/Jacques De Beer

Scientific Report WIV-ISP 2008-2009:
“Spectroscopic detection of counterfeit Cialis®” P.-Y. Sacré, E. Deconinck, T. De Beer, P. Courselle, R. Vancauwenberghe, P. Chiap, J. Crommen, J.O. De Beer

Namaakgeneesmiddelen – Schijn bedriegt.
Medi-sfeer 346, 13 , 11 februari 2010
Patricia Courselle en Jacques De Beer

Validering van analysemethodes bij kwaliteitscontrole van geneesmiddelen,
Medi-sfeer 354, 9, 17 juni 2010
P. Courselle, S. Impens, V. Piette en J.O. De Beer