

Presentation of the phytopharmacovigilance scheme

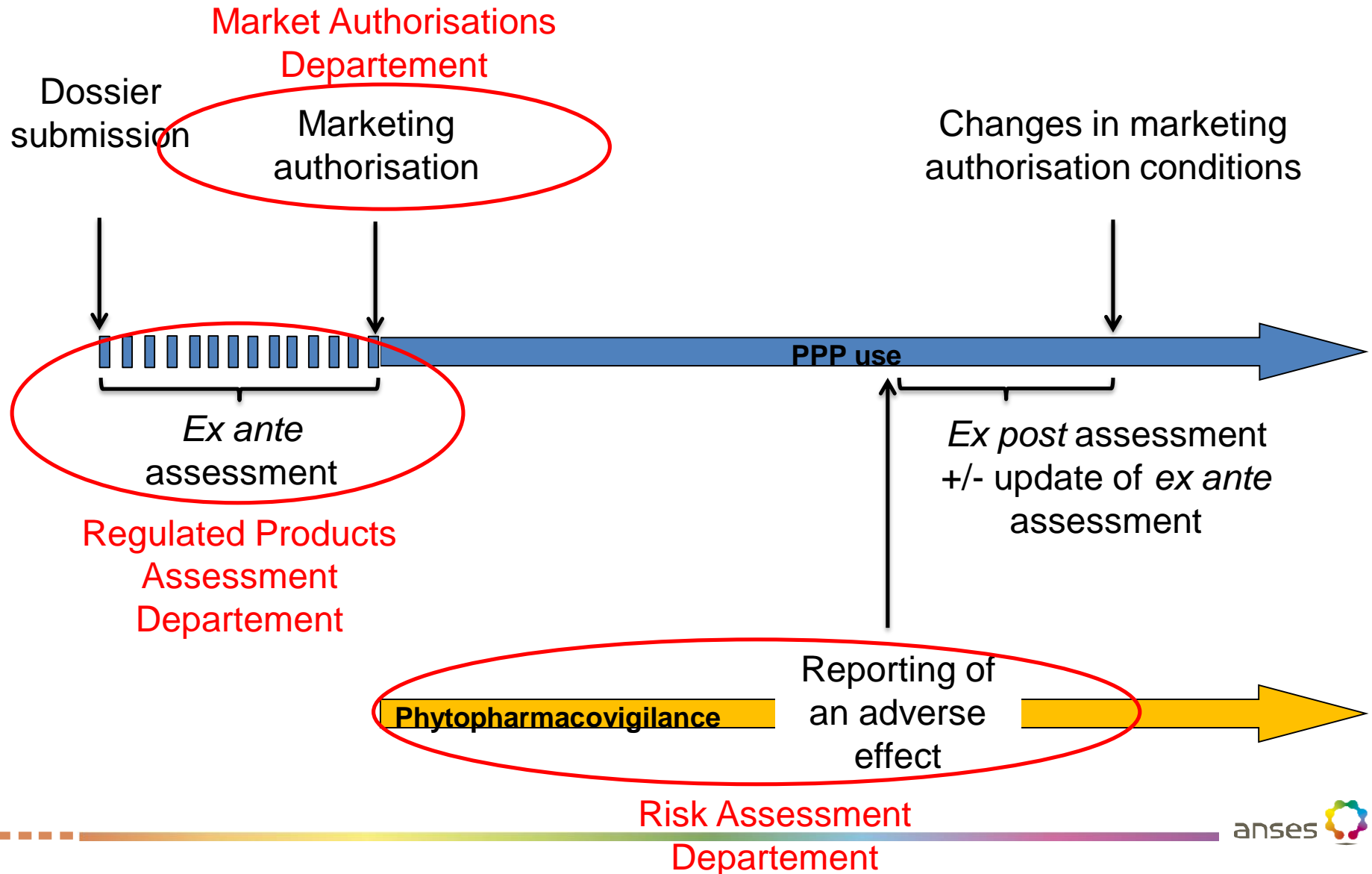
Anses – Efsa advisory forum

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Anses – Risk assessment department



Phytopharmacovigilance in the global PPP regulation framework



What is phytopharmacovigilance?

Act of 13 October 2014 on the future of agriculture, food and forests

Monitoring of the adverse effects of PPP on:

- Humans, livestock including honeybees, crops, biodiversity, wildlife, water, soil and air quality, food, resistance.
- ⇒ In order to detect as early as possible any signals which may require measures to be taken to prevent or limit the risks associated with PPP

Three data sources

- Systematic and periodic data collection produced by the surveillance and vigilance French bodies, gathered in a unified data network
- Reporting obligation to Anses or one of his partner of potentially harmful or adverse effects
 - Article 56 of Regulation 1107/2009 extended to manufacturers, importers, marketers or professional users of PPP, advisers and trainers of those users, in addition to marketing authorisation holders
 - Doctors and veterinarians can also declare adverse effects
 - ⇒ Forms to report effects available on the Anses website
- In order to complete knowledge: *ad hoc* studies on the adverse effects of PPP (specific tax levied on marketing authorisation holders)
 - Improve knowledge of exposure, risks and impacts
 - Investigate reports of potentially harmful or unacceptable effects
 - Strengthen the global network: improve the quality and accessibility of data from the partner networks

Data collected for phytopharmacovigilance

Sales	BNVD	Ineris
Uses	Surveys	Ministry of agriculture
	Agrican, crop-exposure matrices	Centre François Baclesse
Surface water	WFD networks	Ministry of environment
Ground water	WFD networks	Ministry of environment
Bee matrices		ITSAP
Food and feed	Pesticides residues monitoring	Ministries of agriculture and economy
Water intended for human consumption	SISE-EAUX	Ministry of health
Ambient air		ATMO France and Ineris/LCSQA
Human biomonitoring	ENNS, ELFE, ESTEBAN	Santé publique France
Human toxicovigilance	Toxicovigilance	CAP-TV
	Phyt'attitude	MSA
	RNV3P	Anses
Animal toxicovigilance	SAGIR	ONCFS/FNC
	CAPAE-OUEST	ENV-Nantes
Biodiversiy	Biovigilance	Ministry of agriculture
Bees		Ministry of agriculture
Resistances		Ministry of agriculture

Examples of harmful or unacceptable effects notified

- Phytotoxicity of a fungicide in vineyard reported by *a MA holder*
 - Withdrawal of the marketing authorization
- Suspicion of clustered paediatric cancers in a wine-producing area reported by *the national public health agency* (Santé publique France), partner of Anses for phytpharmacovigilance
 - Study in course at the national level on the basis of all the cases of paediatric cancers in France: relationships with PPP exposure?
 - Study on exposure of residents of agricultural areas to pesticides
- Maximum residue limits being exceeded for apples by a herbicide used for cereal crop growing reported by *a MA holder*
 - Change of agricultural practice ?