



News Flash 4










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Key issues for the animal health industry in Europe *Feedback from CNA members*




As a result of the first “special Covid-19” call on 19 March, National associations were asked to liaise with their respective authorities and to present them with seven concerns of importance to the animal health industry. CNA members shared their feedback with the Secretariat. Below a short summary of the answers received for each of the seven questions. In the pages that follow, you will find detailed information per country for each question.

1. Most associations have regular if not daily **contacts with their National authorities** (BE, DE, DK, FR, GB, IE, IT, NL, NO, PT, SP, SE). In some countries however authorities are more reactive than pro-active (PO) or associations are informed but not involved (CZ, SK). Two countries are waiting for the authorities to include them (GR, HU)
2. In most countries, when the human **manufacturing sites are prioritised**, so are the animal health sites (BE, CZ, FR, GB, HU, IE, IT, NL, SP, SK). First sign received in the global supply chain that human manufacturing takes precedence (DE). In others the associations are waiting for this status (GR, PT). The question is just not relevant in other countries (DK, SE, NO) as there is no special status for any manufacturing sector (PO).
3. Where countries have created a category for “**essential goods**” **veterinary medicines** are included (BE, CZ, DK, GB, IT, NL, SK, SP). Agriculture and veterinary services have been officially acknowledged as relevant for the system (DE). In other countries such a category does not exist (FR, HU, IE). Finally, in some countries National associations are waiting for a response or legislation to be adopted (GR, NO, PT, POL, SE)
4. Where **lockdown** is in force, the animal health sector is exempted (BE, CZ, GB, IE, IT, SK, SP). In other countries there is no lockdown (FR, DK, HU, NL, NO, PO, PT, SE). Agriculture and veterinary services have been officially acknowledged as relevant for the system (DE).
5. **Maintaining batch release support** does not seem to be an issue in most countries (CZ, DE, DK, GR, IE, NO, PO, PT, SK). In three countries support is being given (BE, NL, SP). In another three they are waiting for a response from their authorities (FR, HU, IT).
6. It appears most **authorities take a pragmatic and benefit/risk-based approach** when there are delays to routine compliance activities such as GMP inspections due to restrictions (B, CZ, FR, GB, IE, NL SP, SK). Other countries are not receiving any complaints from their members (DE, DK, GR, NO, PO, PT, SE). Two countries are waiting for a response from their authorities (HU, IT).
7. **Asking authorities to be allowed priority testing of COVID-19** to avoid unnecessary lockdowns of animal health manufacturing plants in case an employee is suspected: all countries answered that there was no routine testing in place. No country either has identified workers in the animal health sector as a priority sector. One country is waiting for an answer to have its employees considered as “essential workers” as this status then allows for special treatment (SP), other countries have general procedures to be followed by all employers irrespective of the company’s activity (FR, CZ, SK, PL) In one country for example it’s not possible to tackle this at national level as the Health system is handled on a Regional basis and every region applies its own protocol (IT).

1. The animal health sector is included in all discussions and dialogues concerning measures linked to Covid-19 organized by authorities at national level (Ministry of Health – MoH, agencies etc.).	
Country	
	<u>Belgium</u> This is the case
	<u>Czech Republic and Slovakia</u> CZ Animal health is mentioned during some (dedicated) discussions/dialogues in country. The activity is on Ministry of Agriculture, State Veterinary authority and National agencies. We are in contact with the Veterinary and Veterinary medicine authority – but we are not included into the discussions as an active participant. SK Similar situation is observed in the country.
	<u>France</u> Daily dialogue with the authorities.
	<u>Germany</u> Yes, to a certain extent. Proactive outreach by the authorities is limited due to tight work situation.
	<u>Greece</u> We have informed the relevant Ministries to include us
	<u>Hungary</u> We are not involved yet. It is managed by the Authority and our NA (National association) who have requested involvement.
	<u>Ireland</u> Yes, we are on a regular basis
	<u>Italy</u> Regular dialogue with the authorities.
	<u>Nordic countries</u> DK Weekly TC with Danish Medicines Agency, e-mail correspondence with Food Agency SW E-mail correspondence with Swedish Medicines Product Agency NO E-mail correspondence with Norwegian Medicines Agency & Food Agency
	<u>Poland</u> We are heard when we go to them for answers – but authorities proactively do not reach out to us.
	<u>Portugal</u> Yes we are included.
	<u>Spain</u> Veterindustria maintains daily and fruitful contacts with the main Ministries and stakeholders such as the Ministry of Health, Ministry of Industry and Ministry of Agriculture. Also, with the Spanish Medicines Agency both Department of Veterinary Medicines and Department of Inspection and Control. We maintain contacts with the Chemical Federation, Human Medicines, Food and Drink Spain, Feed Association and Livestock organisations. Also, with Council of Vets and petfood Association.
	<u>The Netherlands</u> Yes we are included.
	<u>United Kingdom</u> Yes we are included.

2. Member states treat animal health medicine and vaccine manufacturing sites as they would treat human pharmaceutical manufacturing sites and therefore prioritize their ongoing operations.	
Country	
	<u>Belgium</u>
	The pharmaceutical industry is treated as a whole with no distinction made between human and veterinary medicines.
	<u>Czech Republic and Slovakia</u>
	Both countries recognize animal health medicine and vaccine manufacturing sites as important and strategic items of concern
	<u>France</u>
	Yes, animal health medicine and vaccine manufacturing sites are treated equally
	<u>Germany</u>
	No confirmation on that, but the veterinary sector has been acknowledged as “relevant for the system. Information received, that international suppliers react to increased demand on human side and thus veterinary sector is supplied in second line. This is no unexpected, though.
	<u>Greece</u>
	We are waiting the response of Greek government to include the vet business in the supply of protective material (gloves and masks, antiseptic solutions)
	<u>Hungary</u>
	Yes, animal health medicine and vaccine manufacturing sites are treated equally
	<u>Ireland</u>
	Yes, animal health medicine and vaccine manufacturing sites are treated equally
	<u>Italy</u>
	Yes (see question 3)
	<u>Nordic countries</u>
	Not applicable in DK, SW, NO.
	<u>Poland</u>
	No special decree for any manufacturing to get a special status this also naturally applies to human & veterinary manufacturing sites.
	<u>Portugal</u>
	We are in contact with our National agency.
	<u>Spain</u>
	Spain has declared the state of alarm (<i>extended for 15 days more</i>), veterinary medicines have been considered an essential good, along with human medicines. The Spanish Medicines Agency has published the following statement: “The Spanish Agency of Medicines and Health Products (AEMPS) wants to state that the veterinary medicine sector is strategic to protect the food supply to the population, maintain the health status of farms and prevent the transmission of disease to people. Therefore, continuity in the manufacturing, distribution and supply activities of these medicines must be guaranteed. The movement of people and the transport of essential products to develop these protected activities preserve, except for force majeure and in a case-by-case analysis”. AEMPS has also declared (in a note) that the pharmaceutical industry (including animal health industry) is an essential industry.
	<u>The Netherlands</u>
	Until now, the Netherlands appointed vital sectors for employees that may bring their children to childcare. Food production incl. suppliers to farmers, is one of these vital sectors. Veterinarians for companion animals can do their work, taking into account the advises of the government such as keeping distance of 1,5 meters and stay home when one member of the household has fever.
	<u>United Kingdom</u>
	Yes, in the UK animal health medicine and vaccine manufacturing sites are treated as human pharmaceutical manufacturing sites and therefore prioritize their ongoing operations

3. Consider veterinary products as essential goods and veterinarian activities as essential services	
Country	
	Belgium This is the case.
	Czech Republic and Slovakia CZ veterinary activities hasn't been restricted. Veterinary service is ongoing. The priority is given to the veterinary products. Equal to human one. SK the same approach has been taken - veterinary activities hasn't been suspended. Veterinary medicine is prioritized.
	France The government's policy is to ask from all industry sectors to provide "minimum service to the economy" In case of excessive absenteeism, each company would decide to refocus on production or the service it considers to be a priority (therefore no list of "priority sectors")
	Germany Building on assessment given in the Commission communication on transport. Information received that the measures currently agreed between the federal government and the Länder to reduce social contacts do not affect the care of animals in human care. Veterinary clinics and medical practices can remain open. Access control is established. Agriculture and veterinary services have been acknowledged officially to be relevant for the system. This also helped to address cases where delivery of VMPs into restricted zones in Germany was held up.
	Greece We have requested for it. We haven't received any final response until now.
	Hungary Yes, vet clinics and pharmacies can normally operate as human pharmacies. Other shops (except food, gas stations) have to close at 15.00.
	Ireland We have a National decree since 24 march where veterinary medicines are specially mentioned.
	Italy <u>INDUSTRY</u> Pharmaceutical Industries, included Vet pharmaceutical, have been considered ESSENTIAL (They will continue business as usual) - Wholesalers and Retailers of pharmaceutical products, included Vet products, have been considered ESSENTIAL (They will continue business as usual) - Feed mills have been considered ESSENTIAL (They will continue business as usual) <u>SERVICES</u> Veterinarians have been considered ESSENTIAL SERVICES (They will continue business as usual) Ground transport for all the products coming from ESSENTIAL Industries have been considered ESSENTIAL SERVICES and they will continue business as usual. For ground transport lorry drivers must adopt special precautions when goods must be delivered in some areas called "RED ZONES"
	Nordic countries DK essential goods + essential services SW no decision yet on essential goods + all vets categorized as essential NO: decision on VMP yet (in the works) + vets in food chain deemed essential. Companion animals probably to follow
	Poland Not yet.
	Portugal Legislation on "essential activities" has not yet been published. However National Agency wrote us that Veterinary medicines will be included as essential activity (production and distribution).
	Spain This is already the case, as stated in the note released by the Spanish Medicines Agency. This message is being reported to the high level discussing regarding Covid – 19 at both Ministry of Health and Ministry of Industry in order to keep considering animal health as a priority/strategic sector in case further restriction are considered.
	The Netherlands Yes.
	United Kingdom Veterinary medicines (not products) are specified, vets for emergency and livestock work; food production being the priority

4. Exempt animal health manufacturing and research sites, distribution centres from lockdown requirements (Animal health companies are all of course committing to take all the necessary precautions required to address the Coronavirus threat - social distancing, hygiene, etc., whilst maintaining Exempt animal health manufacturing and research sites, distribution centres from lockdown requirements essential operations)	
Country	
	<u>Belgium</u>
	The entire pharmaceutical industry (human and veterinary) is considered an essential industry
	<u>Czech Republic and Slovakia</u>
	CZ & SK - yes, animal health manufacturing and research sites, distribution centres are exempt from lockdown requirements
	<u>France</u>
	Not relevant as no lockdown requirements are announced.
	<u>Germany</u>
	Mainly relying on assessment given in the Commission communication on transport, however agricultural sector for food supply and veterinary services are acknowledged to be relevant to the system.
	<u>Greece</u>
	Yes, we continue the operations under the instructions of the Authorities
	<u>Hungary</u>
	Not relevant as no lockdown (yet).
	<u>Ireland</u>
	We have a partial lock down – retail for consumer goods but agriculture inputs with specific mention of vet med are prioritised and remain open.
	<u>Italy</u>
	Yes, we continue the operations under the instructions of the Authorities
	<u>Nordic countries</u>
	DK, SW & NO - no lockdown in any of the three countries
	<u>Poland</u>
	There is no lockdown in our country – probably there will not be one before the 10 May elections. Should a lockdown be decided we are confident that we would obtain exemptions.
	<u>Portugal</u>
	For the moment no complaints from our Members.
	<u>Spain</u>
	This is already the case, as stated in the note released by the Spanish Medicines Agency.
	<u>The Netherlands</u>
	There is no lockdown, so manufacturing sites are still in operation. We have discussed the situation when the government would decide to install a lockdown. Under these circumstances, veterinary services and medicines are considered essential operations in line with the OIE statement.
	<u>United Kingdom</u>
	Yes, animal health manufacturing and research sites, distribution centres are exempt from lockdown requirements

5. Maintain batch release support in countries that require this, including release testing	
Country	
	<u>Belgium</u>
	This support is given.
	<u>Czech Republic and Slovakia</u>
	CZ & SK: such incidents have not been reported so far
	<u>France</u>
	This point is on the agenda of discussion with our Agency
	<u>Germany</u>
	No contradicting information on this. The competent authorities also have a certain flexibility with regard to inspections and related certifications.
	<u>Greece</u>
	No real problem until now
	<u>Hungary</u>
	We proposed changes due to Covid-19 to the Authority and waiting for their response.
	<u>Ireland</u>
	We don't have much manufacturing. For the ones in place everything is functioning normally.
	<u>Italy</u>
	We have already asked for clarification to our MOH. We are waiting for the answer
	<u>Nordic countries</u>
	DK: No batch release undertaken by DKMA (MA-holder) NO: No batch release undertaken by NoMA (MA-holder)
	<u>Poland</u>
	No real problem until now
	<u>Portugal</u>
	For the moment no complaints from our Members.
	<u>Spain</u>
	AEMPS is maintaining all procedures working for our sector, including this.
	<u>The Netherlands</u>
	Yes, the national competent authority is functioning.
	<u>United Kingdom</u>
	Believe so, has not been a point of discussion but regulator has confirmed wish to support industry as far as possible,.

6.	Take a pragmatic and benefit/risk-based approach when there are delays to routine compliance activities such as GMP inspections due to restrictions.
	Country
	<u>Belgium</u>
	This is the case
	<u>Czech Republic and Slovakia</u>
	CZ & SK - yes, our authorities are taking pragmatic approaches
	<u>France</u>
	This is the case.
	<u>Germany</u>
	The competent authorities have a certain flexibility with regard to inspections and related certifications. Right now, we do not have confirmation by practical experience.
	<u>Greece</u>
	At the moment we haven't received any complaints on it. Not a lot of manufacturing veterinary sites
	<u>Hungary</u>
	We proposed changes due to Covid-19 to the Authority and waiting for their response.
	<u>Ireland</u>
	The authorities are taking a pragmatic approach.
	<u>Italy</u>
	We have already asked for clarification to our MOH. We are waiting for the answer.
	<u>Nordic countries</u>
	DK, SW & NO - no indications that authorities are not being flexible.
	<u>Poland</u>
	For the moment no complaints from our Members.
	<u>Portugal</u>
	For the moment no complaints from our Members.
	<u>Spain</u>
	This request has been communicated to AEMPS. Nevertheless, all administrative procedures have been suspended for the moment.
	<u>The Netherlands</u>
	Yes, our government acts pragmatic on compliance activities.
	<u>United Kingdom</u>
	Yes, regulator has confirmed wish to support industry as far as possible

7.	Should an employee be suspected, allow for priority testing of COVID-19 to avoid unnecessary lockdowns of manufacturing plants.
Country	
	<u>Belgium</u>
	For the time being there is no routine testing in place.
	<u>Czech Republic and Slovakia</u>
	CZ Employee is obliged to announce any change in his/her health status. There is general monitoring available. Once there is a suspicion – the tracking/history of contact is started. Respective employee must follow recommendation of the public health services – quarantine for 14 days. Moreover – there are other measures in place. SK There are recommendations how to proceed if there is a suspicion. Similar steps are to be taken.
	<u>France</u>
	The procedure is on the web site of the Government : click here for more information.
	<u>Germany</u>
	No confirmation of this yet. Sovereignty of the Lander allows for own protocol. So far federal decisions need implementation at Lander level.
	<u>Greece</u>
	We don't have any feedback about this for the moment.
	<u>Hungary</u>
	Has not been an issue till now, but we will take it up with the Authorities.
	<u>Ireland</u>
	We haven't requested this yet. Split teams are in place. Will consider this as of now.
	<u>Italy</u>
	It is not possible to fight for it at National level as the National Healthy system is on a Regional Basis. Every region applies its own protocol.
	<u>Nordic countries</u>
	DK, SW & NO: not applicable in these 3 countries
	<u>Poland</u>
	We don't have any feedback about this at the moment. No testing but public health procedures apply as for all other employees.
	<u>Portugal</u>
	For the moment no complaints from our Members.
	<u>Spain</u>
	AEMPs has delivered some recommendations for the industry, including for COVID-19 testing: "The detection of SARS-CoV-2 infection is recommended in those workers assigned to tasks considered essential". We are in contact with AEMPS to clarify if suspected cases (workers assigned to essential tasks) will be considered for priority testing.
	<u>The Netherlands</u>
	We do not have a priority testing policy. Generally, a person should stay home when he/she has a cold or coughs. When one person of the household has fever, the whole household should stay at home. Vital sectors are exempted. Employees in these sectors should stay home when they have a fever (in consultation with the employer). Veterinary medicines for food producing animals are considered a vital sector.
	<u>United Kingdom</u>
	We have called for this, unknown at the moment.