Ref. Ares(2014)1499664 - 12/05/2014

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate D - Health systems and products
D4 – Substances of Human Origin and Tobacco Control

Brussels,
SANCO D4/MA/ac ARES (2014)

Meeting of the Competent Authorities on Blood and Blood Components

6 and 7 November 2013

Summary Report

Participants:

Representatives of all 28 Member States, with the exception of Bulgaria and Malta, were present. Representatives from ECDC, EMA, WHO, the Council of Europe (CoE) and EBA were also present. So were representatives of Serbia, the Former Yugoslav Republic of Macedonia and Turkey.

European Commission – SANCO D4, SANCO D1 and SANCO B2.

Chairman: Dr Stefaan Van der Spiegel

1. ADOPTION OF THE AGENDA

The agenda was adopted without any changes.

The Commission announced that the German competent authority (CA) for tissues & cells (T&C) has made a proposal to develop dedicated rules of procedure (RoP) for the competent authorities on substances of human origin expert group (CASoHO 01718 in the Commission register of expert groups).

This would cover the meetings of the competent authorities in all SoHO sectors (blood, organs, and tissues & cells). Once finalised and agreed within the T&C group, the proposed RoP will be presented to the blood and organs CA groups for comments and potential changes. If and when all 3 groups agree to the draft rules, they will be considered as adopted and replace the standard rules of procedure for expert groups which are currently being used.

2. SURVEILLANCE AND VIGILANCE: UPDATE ON INFECTIOUS DISEASES RISKS

2.1. West Nile Virus (WNV)

Italy, Greece, Hungary, Romania each reported on the situation in their country. This included an overview of occurrences during the past season, as well as measures taken to mitigate the risk of WNV transmission by blood transfusion, in particular through NAT testing. Good cooperation between surveillance and vigilance offices, including in the veterinary and the entomological field, were considered to be very useful to prevent the spread of WNV through blood. There were some limited impacts reported on blood availability in parts of RO (Bucharest) and EL (Athens) where some healthcare activities were delayed due to a lack of blood components , i.e. elective surgery , transfusion of thalassaemia patients and oncological cases requiring platelets transfusion.

2.2. Dengue

France presented an update on Dengue (in particular for its overseas territories) and an overview of the preventive measures implemented during the 2012/2013 season for blood, organs, tissues and cells. There was general interest in the criteria and definitions used. Portugal also presented an overview of the situation on Madeira.

2.3. Malaria

Greece presented information on the 2013 malaria season. As of the beginning of November, only 3 locally acquired cases had been reported, 2 in the area of Alexandroupolis and 1 in the area of Karditsa. No locally acquired cases were reported in Lakonia.

2.4. ECDC updates

ECDC presented its work plan, including the development of a knowledge library on donor derived infections (covering 6 priority diseases). ECDC also presented work on the donor qualification and risk assessment for HIV, HIV/AIDS surveillance, and the satellite meeting on malaria (which will result in a technical paper).

ECDC agreed to assess the feasibility and interest in collecting national blood donor test results to build an EU overview, as many Member States have national data on the number of tested blood donations for diseases like HIV and hepatitis. AT, CY, CZ, EL, ES, IT, LT and RO volunteered to help ECDC in this work. It was however stressed that any recommendations based on this data should be made at national level in function of local situations rather than for the entire EU.

2.5. Hepatitis E Virus

ECDC presented general information on Hepatitis E, including the current situation in MS, SARE notifications for blood and blood components, and risk assessments and prevention of transmission of HEV by blood and blood components.

The situation in France was also presented. In the south of France, approximately 1 in 2000 donors test positive for HEV. To address this issue, NAT screening tests for HEV were introduced by Etablissement Français du Sang (EFS) for FFP-SD and military centres in December 2012. As of 2013, plasma pools for military use are also screened.

Several Member States already have measures in place to address the risk of HEV transmission. In early 2014, Germany will publish a scheme on HEV including pathogen description, illness description, transmission, methods to avoid transmission. EFS is publishing an article on the disease in the south of France. The UK is doing a look back study in patients for HEV. EBA has also studied HEV for two years and has so far concluded that the methods used for serological testing are weak.

It was also mentioned that there are limited inactivation methods available, which mainly involve heating. This poses particular problems for plasma and transmission through plasma has been reported. EMA also mentioned that they are studying HEV. The Biologics working party will look at this during its 2014 work programme, including a workshop end 2014. Some NCA's expressed interest in participating in such a workshop. It was concluded that the topic will need to be further addressed in future meetings.

2.6. Other

Member States had no further information to share regarding communicable diseases.

3. SERIOUS ADVERSE EVENTS AND REACTIONS (SARE) AND ALERTS

3.1. Preliminary SARE Annual Report exercise 2013

The Commission made a short presentation of the 2012 SARE data (reported by all countries). Limited indicators were presented, as it was decided by the Haemovigilance Working Group (HVWG) in 2012 that the data is currently not reliable enough to draw firm conclusions. The HVWG will continue to improve the collection and reporting of SARE data. In general, the Member States were very pleased with the work.

A discussion on further improvements followed. This included the collecting information on discard rates, performing root cause analysis for SAR and SAE, and delaying data collection to facilitate reporting. Some MS expressed the desire to move towards a less complex data collection with a longer deadline in order to have all data available at national level when they are collected in this EU exercise. It should however be noted that the 30 June deadline is a legal requirement and the current data collection is the result of many years discussion with the HVWG.

It was suggested that root cause analyses should be further developed in the MS, as human errors are often mentioned as source of an SAE, without understanding their cause. Requests were also made to verify if further data analyses could be undertaken to understand ABO-related SAR and the safety of platelet collections through apheresis. These questions will be discussed with the HVWG.

3.2. Rapid Alerts Blood (RAB)

The Commission reported on the RAB platform which was developed with the help of the HVWG and will be launched in February 2014. MS were asked if they would like further training courses for the platform. CY, CZ, EL, FR, FYROM, LT, LV, NO, PL, PT, RO, and UK showed interest in attending a session in January 2014. The Commission will explore possibility of further online trainings.

The members of the HVWG and participants added that they mainly expect epidemiological or medical device alerts. In this context, it was reiterated that it is the responsibility of each

NCA blood to contact its national counterpart authorities on medical devices, or other affected sectors, to inform them of alerts sent through RAB. A joint decision can then be made whether further alerts should be launched in the relevant sector-specific alert networks, informing all relevant national authorities in the EU.

MS were reminded that while an NCA in one MS can launch an alert or send recommendations, it remains the responsibility of each competent authority to assess the situation within its own Member State and make the decision whether or not to take any corrective actions.

It should also be noted that the main role of the Commission is to facilitate communication. Although the platform is hosted by the Commission, the responsibility to launch and update alerts remains with the competent authorities.

EBA expressed interest in taking part in the RAB platform. The Commission explained that the tool is designed for use by national authorities which link to their national blood establishments.

3.3. Follow-up on reported cases (other than infectious disease alerts)

In 2013, there were three cases of European alerts in the blood sector related to medical devices. For one of the cases, France mentioned that they would share some supplementary information soon.

There was also a discussion on which authority is responsible for launching and managing alerts on medical devices. Should it be the NCA who first receives the information that launches the alert or should it be launched by the MS where the supervisory medical device authority is located. It was generally agreed that the blood authority in the country where the device is manufactured should play the leading role. However NCA that are made aware of an issue should launch the alerts as soon as possible, regardless whether the device is manufactured in their country or not.

4. REGULATORY MATTERS: POINTS FOR INFORMATION

4.1. Transposition check – state of play

As of the end October 2013, the transposition check (TC) has been closed satisfactorily for 23 MS. One infringement proceeding is on-going, Two clarifications and one corrigendum are outstanding, for which the Commission is currently waiting for confirmation of the official adoption of amendments to national legislation which will close these TCs. Subsequently there is now also a pilot procedure ongoing which was not part of the original TC.

4.2. Survey on the implementation of the EU blood and blood components Directives (Article 26 of the Directive 2002/98/EC)

The Commission has received replies from 25 MS, NO and LI. Reminders have been sent to AT, ES and UK to send in these data in order to fulfil the legal requirement of Art. 26 of Directive 2002/98/EC. Although the replies are still being analysed, some first results were presented and triggered interesting questions.

Questions were asked on the number of traceability systems reported and the possibility of introducing an EU-level system was raised. Other Member States explained, however, that they cannot change their current systems. The Commission clarified that, in contrast to T&C legislation, EU legislation on blood does not provide for a uniform EU traceability system (but does require that every MS has a traceability system in place).

There was a request for more explanatory fields in the questionnaire allowing for opportunities to explain complex national situations. Definitions and the interpretation of certain questions should also be better clarified. CoE remarked that the results do not always correspond with findings in the CoE surveys.

There were questions whether these survey results would lead to a revision of the blood legislation. The Commission clarified that no decision on a potential revision has been taken and cannot be expected under this Commission's mandate.

4.3. Survey on promotion by the Member States of voluntary unpaid donations (Article 12.2 of Directive 2002/98/EC)

The Commission presented plans for the latest VUD survey, to be launched late 2013/early 2014. The overall chapters and structure were presented, as well as some definitions, including shortage and self-sufficiency, to ensure a common understanding in the context of this survey. These definitions were welcomed for the purposes of the survey but it was made clear that these should not be considered official EU definitions.

It was clarified that the survey will include specific questions for blood/blood components and plasma derivatives. Plasma derivatives are also covered to ensure that a complete picture of blood donation in the EU is obtained. Although plasma derivatives are pharmaceuticals, the donation, collection and testing of their starting material (plasma) is subject to the blood legislation.

Participants were invited to send to SANCO written inputs/suggestions on the VUD survey.

4.4. Definitions of the Plasma Master File (PMF) related to inspections and inspection intervals of blood establishments

During the previous NCA meeting, MS discussed that inconsistencies concerning terminology, in particular concerning (mobile) collection sites and the applicable inspection regimes. There was a worry that this might lead to different interpretations, which may in turn result in confusion and potential safety risks.

It was considered important to further develop common thinking, given the difficulty of inspecting all sites on a 2-year basis, as laid down in Art. 8.2. A small sub-group was therefore asked to look into nomenclature and inspection intervals (AT, DE, IE and UK (lead), together with EMA).

A new proposal classifying BEs according to their structure was presented. It was explained that depending on the activities performed by the BEs different risk levels could be expected. A potential solution could therefore be to use risk-based inspection systems, better focusing inspection resources.

The definition of "inspection" was also discussed. Similarly to T&C legislation, a proposal could be made to allow for different types of inspection (for example on site or desk-based).

The participants welcomed reflections in this area, to allow for a more risk-based approach. Some concerns were, however, expressed on the potential confusion resulting from new non-binding definitions, which are not laid out in legislation.

The Commission explained that it will need to look at the compatibility of this new proposal with the current legislation, and whether an amendment would be required to update EU blood legislation in this area.

4.5. Medical Device Directive Revision

The Commission updated on the state of the negotiations on the Medical Devices and in-vitro Diagnostic Medical Devices revision. On 22 October 2013, the European Parliament voted in plenary session on the texts as amended and gave a mandate to the Rapporteurs to start the inter-institutional negotiations. In the Council, under the Lithuanian Presidency and the future Greek Presidency, the examination of both proposals is on-going, with a view to achieve a first Reading adoption in early 2014, before the new EP elections.

Some of the EP's amendments are of a specific interest for the blood sector: in-house exemptions for Class D in-vitro diagnostics, medical prescriptions for diagnostic tests, and scrutiny of high risk devices.

NCAs were invited to look more closely to their specific points of interest and to relay any concern through their respective MS representatives in Council Working Party on Medical Devices.

5. PRESENTATION OF KEY INTERPRETATION ISSUES AND DISCUSSION

5.1. Acceptance criteria of blood donors aged > 65

According to Annex III of Commission Directive 2004/33/EC, donors over the age of 65 can only donate blood and blood components with the permission of the physician in the blood establishment, to be given on an annual basis. However, Finland sought clarification as to whether this permission should be given on an individual or group basis.

Finland explained that donors in Finland can safely donate blood until at least the age of 71, provided that they meet all other relevant acceptance criteria. Other countries presented their national approaches. AT, BE, DK, EL, NL, and UK have all raised the maximum age from 65. In contrast, SK, RO and FYROM have an upper age limit of 65. Cyprus reminded the group of the need to check the impact of anti-coagulants. Finland also mentioned that they have such a list of medicines to verify, as these give an indication of the diseases.

The Commission recognised that the wording of the EU legislation is silent on whether a decision is to be made on an individual basis or can be made for a group as a whole, but recalled that such permission should be granted by the physician *in the blood establishment*. The organisational structure of blood establishments within any given country will therefore determine whether such a decision could be taken at a *de facto* national level, which would appear to be the case in certain MS.

The Commission informed the group that in the implementation survey seven out of twenty-seven countries indicated they wanted to review the age criteria.

A possible amendment of EU legislation would need to look at evidence on donors and the quality of blood from donors. It was mentioned that any potential revision of related legislation should take account of the CoE recommendations. The group indicated that it was a worthwhile topic for CoE to develop within CDPTS. CDPTS could also consider collecting MS practices and developing previous work by IHN and ISBT.

5.2. Updated information on a potential revision of the Directives

The Commission explained that no decision on any potential revision has been taken, and won't come under consideration until a new Commission is in place.

6. PRESENTATIONS OF PROJECTS, ACTIVITIES AND EU FUNDING

6.1. DG REGIO Structural Funds

The Commission presented information on the set-up of structural funds managed by DG REGIO and DG EMPL. Possible areas of funding in the SoHO sector are central or decentralised capacity building to support transfusion and transplantation activities, or the set-up of dedicated databases for donor recruitment, donor follow-up and recipient/patient follow-up for specific population groups. National authorities in eligible Member States, with an interest in using of structural funds to develop transplant capacity/activities are encouraged to inform DG SANCO.

6.2. Council of Europe (CoE) update

CoE provided an update of their activities, including the 17th edition of the Guide to the preparation, use and quality assurance of blood components, the development of guidelines for quality systems, a symposium on clinical use of fresh frozen plasma (beginning 2015), the resolution of risk behaviours for blood donation and activities in blood proficiency testing.

Good Practice Guidelines for elements of the Quality system were developed in CoE project TS066 (co-funded by the Health Programme). There was interest in more official recognition of this work. The outcomes could e.g. be used in upcoming training programmes for inspectors. The Commission agreed to further discuss with the CoE the issue of how to make these guidelines available, taking into account the original legal mandate of the Commission to develop such guidelines laid down in Article 2 of Commission Directive 2005/62/EC and the subsequent work on their development within the framework of the abovementioned project.

In relation to risk behaviours for blood donation, CoE will be set-up a working group early 2014 in order to specify deferral criteria and minimise the risk of discrimination of certain population groups, potentially allowing a more segmented/individualised deferral of candidate donors.

Participants expressed interest in CoE activities on blood proficiency testing scheme (BPTS, comparing performances of test labs). B-PTS focuses on the needs of BEs, including small and low budget establishements, and covers NAT testing, serology testing and immunohemotology (tests required by EU legislation are prioritised).

6.3. Training programme for inspector of establishments (CATIE)

A member of the CATIE consortium presented the final outcomes of the project. Many participants expressed interest in receiving copies of the manual for trainees. The Commission will verify how to best disseminate these materials. These materials could also be used for the work of the CoE.

6.4. Overview of the blood market (Creativ Ceutical)

The Commission gave an overview of the project and process. Overall the project has been difficult due to the limited availability of data (which is fragmented, outdated and not public) and by some fundamental questions, which are discussed controversially (e.g., payment of donors, cross-subsidization of actors, and other issues). Following criticism from Member States and stakeholders, the Commission has asked the contractor to include information from EU-wide consistent data sets by CoE and MRB (Market Research Bureau, a market analyses bureau focused on plasma derivatives). Comments from 16 MS have also been integrated into the report.

The Commission will send new country reports to MS for further comments by end 2013. The Commission also asked participants to provide alternative data sets where MS believe the presented data is incorrect. The main stakeholder associations will also be asked to provide inputs.

It was made clear that, although the contractor has finished its work, the reports cannot yet be considered finalised, as long as the Commission has not concluded its verification. Where possible, the Commission will also cross-check with the results of the implementation survey.

EBA and CoE announced the plans for a working group on the interdependence between the blood and plasma sectors, including stakeholders of different sectors.

6.5. WHO update

WHO provided an update of their activities, including World Blood Donor Day, a global policy consultation which put forward a declaration highlighting the importance of self-sufficiency from VNRBD, the listing of whole blood and blood components on the WHO essential medicines list and a global consultation on vigilance in SoHO which draws on the Notify project. It was also communicated that WHO data could be used as a complementary data source on blood collection.

7. ANY OTHER BUSINESS

7.1. Intra MS agreements to supply surplus blood collection

Although surplus blood exchange falls outside of the EU's mandate on quality and safety, some MS have expressed interest in exploring approaches to exchange blood (components), in particular during crisis situations.

Practical elements like labelling and donor consent will first need to be addressed, as well as vigilance and traceability. However, as general principle, it should be remembered that each country should work towards self-sufficiency addressing supply as well as demand.

An informal Working Group presented plans to create a template to collect information on existing contracts for exchange, conditions and experiences. It was indicated that previous work by EBA and WHO could also be used for this purpose.

It was agreed that a list should be elaborate of all the elements needed to a safe and effective exchange of blood. As a next step the Working Group will email MS this template.

7.2. Acceptance criteria for bone marrow donors

Poland asked the group what the time interval between peripheral blood stem cell donation and blood donation should be for the same donor. Haematopoietic stem cell donors are often chosen from the pool of blood donors and this may impact the supply of blood. The role of stimulation factors and the need for blood testing was mentioned. Some MS (NL, DE and FR) mentioned having guidelines for this and will come back with more info.

DOMINIK SCHNICHELS