EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Meeting of the Competent Authorities on Blood and Blood Components

9-10 April 2014

Summary Report

PARTICIPATION:
All Member States were present at the meeting of the competent authorities (CA) on 9 and 10 April 2014. Norway and Turkey, as well as the European Directorate for the Quality of Medicines and Health Care of the Council of Europe (EDQM), WHO, the European Centre for Disease Prevention and Control (ECDC) and the European Medicine Agency (EMA) also attended the meeting. Iceland and Liechtenstein were absent. Former Yugoslav Republic of Macedonia, Montenegro and Serbia did not confirm their presence.

Chairman: Mr Dominik SCHNICHELS (SANCO)

Commission: Ms M. AMIL DIAS, Ms I. SISKA, Mr R. MCGEEHAN, Ms H. Le BORGNE, Mr P. CATALANI (SANCO)

Day 1

1. ADOPTION OF THE AGENDA

The agenda was adopted without any changes.

2. RULES of PROCEDURES (RoP) for SoHO GROUPS

The Commission updated the Member States on the Rules of Procedures (RoP) for the SoHO competent authority' groups including their main provisions. It was highlighted that Art. 6 provides the possibility for group members to express dissenting opinion(s) in the case of a vote. Dissenting opinions are to be reported in the summary reports of meetings. Participants were informed about the obligation to declare any conflict of interests at the start of each meeting.

3. SURVEILLANCE AND VIGILANCE

3.1. Surveillance and Vigilance: update on infectious diseases risks (ECDC)

The ECDC updated Member States on outbreaks of infections transmitted by blood, including Chikungunya, Zika and Ebola, as well as on-going activities regarding blood safety in this field. ECDC noted that there are difficulties with diagnosis of these diseases in the Pacific region.

Regarding a question on maps of risk areas (BE), it was clarified that the current contract does not provide for the development of a map (ECDC). ECDC explained also that it's primary focus will be on defining criteria for donor exclusion, but preparation of a screening strategy will be considered as a potential second step. It was noted that the epidemiological situation needs to be monitored closely, due to this year's mild winter which may increase mosquito-borne diseases in the EU (EL).

3.2. Alerts

3.2.1. Trypanosoma cruzi – transmission via transfusion (BE)

BE presented a case of transfusion-related transmission of Trypanosoma cruzi. It was explained that this was the first case of transfusion transmitted Trypanosoma cruzi in Belgium. Participants were informed that infections are considered to originate from South America. The need for Trypanosoma cruzi screening of at-risk blood donors was highlighted.

3.2.2. Hepatitis E

The competent authorities from of France, Germany and the UK updated the meeting on the risk of hepatitis E infection from blood transfusion. The UK presented results of studies on donor screening, identifying recipients and the outcomes of receiving HEV-contaminated blood or blood components. The studies found that not all recipients of HEV-infected blood were infected (UK). It was emphasised that understanding outcomes is complicated, but data generated from this study are very informative. ECDC noted that another possible source of HEV-transmission apart from blood transfusion was eating contaminated meat.

FR provided information on the risk of hepatitis E transmission by transfusion and provided Member States with haemovigilance data. From 2006 till 2014, 34 cases of suspected transfusion transmitted HEV infections were reported (FR).

DE presented an assessment of blood-borne pathogens. The German competent authority informed the meeting of a substantial increase of reported HEV-cases in Germany. It was noted that this is particularly dangerous for pregnant women. DE stressed that the risk of HEV transmission by blood products has not been sufficiently examined in Germany due to a lack of data and presented two cases illustrating the difficulties in detecting transfusion-transmitted infections.

3.2.3. Follow-up on reported cases of Chikungunya

FR informed the meeting of Chikungunya preventive measures implemented in 2012-2014 for SoHO. This included a Chikungunya preventive strategy, details on Chikungunya alerts and information on the current epidemiological situation.

3.2.4. Follow-up on reported cases of West Nile Virus (WNV)

EL and IT updated participants on WNV. The Italian competent authority presented its approach on precautionary measures for WNV. There have been no cases of WNV transmission through transfusion in Italy so far. In spite of this, the value of early prevention of WNV and financial benefits of this approach were underlined. The role of the mosquito vector index was highlighted with the conclusion that integrated surveillance is essential for predicting WNV epidemics.

The Greek competent authority presented an epidemiologic analysis of WNV cases in Greece from 2010-2013. Ongoing entomological surveillance and research in Greece focusing on detection of WNV in mosquito pools was also presented. It was concluded that increased mosquito abundance could be an early indicator of human infection risk with relevance for public health and blood safety planning.

ECDC noted that diseases require different approaches and in this case preventive measures including donor exclusion should follow the first reported case. In this case, the value of blood screening, though individual NAT testing, was underlined. It terms of surveillance systems, it was clarified that introducing precautionary measures should take into account changes in climate (IT). CZ reported not having detected any WNV cases last year, but asked that other Member States be warned if the situation in Greece and Italy should change.

ECDC and the Commission reminded the group of past outbreaks. FR and IT confirmed having an internal information exchange regarding exclusion criteria for tourists. CZ and DE confirmed exclusion of donors having visited particular countries. FR reported a similar approach, except that tourists from Italy and Spain are only deferred if they have visited particular risk regions.

Based on the data provided by IT and EL, the WNV preparedness plan may need to be updated. Additionally, RO informed on an upcoming meeting with the national health ministry concerning WNV, as they have inadequate funds and lacking support from the veterinary side. The Commission stressed the value of an integrated approach and precautionary measures.

HU reported focusing on deferring travellers from risk areas, as well as training physicians responsible for donor selection. It was stressed that mosquitos can easily move across borders, so neighbouring countries should be aware of possible strategies (ECDC).

The Commission announced that draft legislation will be prepared giving Member States the possibility to accept blood donors coming from WNV risk areas providing that an individual Nucleic Acid Test (NAT) for WNV is negative, instead of the current 28 day deferral period required by Directive 2004/33/EC (Annex III). This is particularly important if there is a shortage of blood donors in a specific region affected by West Nile virus.

3.2.5. Follow-up on reported cases of Dengue

The French competent authority presented dengue preventive measures for SoHO implemented in 2012-2014. The Dengue Preventive strategy, details on dengue alerts and the current epidemiological situation were outlined (FR). PT noted that the outbreak of dengue [in Madeira] is under control and no new cases have been reported.

3.2.6. Malaria

The Greek competent authority presented an overview of general epidemiological data on malaria and blood safety measures. It was emphasised that the public health strategy for preventing malaria had been successful and no any new cases of transfusion-transmitted malaria were reported in Greece during 2009-2013. ECDC reported about a technical document on spatial definitions of areas affected by malaria, which would be presented to the group during the next competent authorities meeting.

3.2.7. Additional information

FI informed the group of a national donor deferral strategy. Male donors having had sexual contacts with other men coming from malaria-affected areas are temporary excluded from donation.

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

4.1. SAE root cause analyses

4.1.1. Transfusion-transmitted bacterial infections

The Italian and German competent authorities provided the group with case study analyses on transfusion-transmitted bacterial infections. IT reported on the contamination of blood components by a contaminated liquid hand wash. Due to a local nature of this incident there was no need for a European rapid alert. DE reported on contamination cases caused by patients using recycled paper to wash their hands.

4.1.2. Transfusion-transmitted viral infections

The Greek competent authority provided the group with a detailed analysis of a SARE case which resulted in a patient´s death ten days after being transfused. After the investigation did not reveal the source of infection, donor skin contamination was considered to be the cause of the reaction.

4.2. SAE classification and SARE reporting exercise 2014

The Dutch competent authority presented various serious adverse events and their possible classification. In addition, the Commission provided the group with details of the 2014 SARE reporting exercise. The Commission informed participants that a PDF template will be sent out in May 2014 with a deadline of 30 June 2014. A proposal to extend the deadline was not accepted due to the fact that the deadline is in the legislation (BE).

Difficulties in reporting SARE uniformly were presented (FR). FR explained that it is currently uncertain exactly what should be reported and there are some differences in understanding of definitions between Member States.

In general, Member States found the Commission´s approach to the SARE reporting exercise very useful. Member States were invited to send to the Commission comments on how to improve the common approach document by 25 April 2014.

Additionally, CZ reported having some difficulties with data collection. The Czech competent authority questioned the value of the data and its interpretation. The

Commission explained that the main purpose of collecting the data is to identify causes of SARE.

Moreover, it was proposed to change the current order in the questionnaire in order to start with a description of event followed by its category and specification (BE). This approach could technically facilitate SAE.

The French competent authority suggested extending the scope of the Directive 2004/23/EC, which is now limited to quality and safety standards, to include patient and donor safety. This approach would ultimately lead to obligatory reporting of all categories of SARE. The Commission will take this into consideration if Directive 2004/23/EC is revised.

4.3. Lessons learnt from the IHN and the ISTARE project

The Greek competent authority introduced the International Haemogivilance Network (IHN) and the International Surveillance of Transfusion-Associated Reactions and Events (ISTARE) project. It was explained how data on adverse reactions and events is being collected and evaluated. It was stressed that the project has an international character and extends beyond Europe. A need for clarification on data differences was expressed (NL). It was explained that collecting reliable data at national level is very difficult, but the database is becoming more and more reliable (EL).

4.4. RAB: Description state of play: Developments and training on RAB platform and update on RATC and Rapid Alert on Organs

The Commission reported that the Rapid alert platform for blood and blood components has been operational since February 2014. There have been no alerts to date. The current situation for tissues & cells and organs was also presented. It was clarified that, for blood sector alerts, the focus is on epidemiological or medical aspects, even if there is the possibility to introduce other types of alerts.

5. REGULATORY MATTERS: POINTS FOR INFORMATION

5.1. Transposition check – state of play

The Commission provided the group with information on an ongoing infringement procedure. It was explained that one Member State still has to communicate final adopted versions of amendments of national legislation. The Commission reminded the group that a preliminary ruling from the European Court of Justice relating to deferrals of MSM is still pending.

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

The Commission gave an update of the current situation regarding the implementation of the EU Blood Directives. The Commission reported that all Member States, Liechtenstein and Norway have submitted the survey. The Commission will keep the competent authorities informed of next steps.

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

The Commission explained to the participants various issues when replying to the survey. If there is no clear `yes` or `no` answer (DE, CZ), the Commission asked that Member States choose the most appropriate answer and submit comments at the end of the section. The group was informed that the Commission will submit a report on voluntary and unpaid donation in 2014.

6. PRESENTANTATION OF PROJECTS, ACTIVITIES AND EU FUNDING

6.1. Risk Based Decision Making project being undertaken by the Alliance of Blood Operators

The German competent authority reported not only on the safety and quality issues, but also to problems with blood-supply and economic aspects. It was recommended that appropriate stakeholders are contacted at national level when searching for a solution for such problems.

Day 2

6.2. Patient blood management (PBM)

An overview of the new patient blood management (PBM) study was presented to the competent authorities. Numerous good practises in the field of blood transfusion were outlined. It was clarified that the project aims to develop an EU guide on good practices for patient blood management based on the three pillars of the PBM concept: anaemia, blood loss & bleeding and transfusion.

DE and TR both reported on initiatives in their countries. Several countries pointed out difficulties in supporting patient blood management due to the lack of national laws in the area (DE, CZ). EL stressed the great value of the project focused on data collection, analysis and implementing measures. It was pointed out that there is a room for improvement by collecting data from the hospital transfusion committees which can provide an appropriate approach for the component authorities (EL). TR informed about the success of an IT study `Smart Transfusion` involving the Social Security Department.

The European Medicines Agency welcomed the initiative and suggested three ways of increasing awareness among the general public: through cooperation with the Council of Europe and the Commission, and making information publicly accessible on the internet. The competent authorities were encouraged to provide relevant data to the project by contacting the contractor.

6.3. Council of Europe (CoE)

The Swedish competent authority raised the problem of test kits and asked for clarification regarding reporting of detected problems. The Council of Europe explained that although they cannot provide a legally binding reports or recommendations, they do contact establishments and suggest appropriate actions. Different standards of inspections in Member States were also outlined. It was suggested that an ongoing project can help to fill this gap. CoE informed about the publication of the good practice guidelines and designating the GTS-group as responsible for their revision. CoE expects

comments for an update of the guidelines by the end of August. The competent authorities were also updated on the TS003-group working on a blood supply management. CoE asked for participants for two new working groups: plasma management and risky behaviours having impact on the safety of blood donation.

6.4. WHO update

WHO presented its strategic framework for blood safety and self-sufficiency. The WHO decision to put whole blood and blood components on the Essential Medicines List (EML) was questioned (FR). It was clarified that WHO does not provide legally binding documents and putting blood on the EML was intended to increase political awareness in the field, provide recommendations and gain more support for blood transfusion at national level. FR pointed out that having blood on the EML raises questions which legislation should apply. In this regard, the Commission stressed that substances arising from human donation could not be treated in the same manner as pharmaceuticals. WHO agreed to take this into account and suggested that a special program for biological products of human origin could be a potential solution. WHO will provide further information in writing.

It was also explained that WHO intends to introduce ISBT 128 as a global coding system for blood components and tissues & cells to ensure their traceability. It was agreed that there should be a reflection on using ISBT 128, as this coding system charges fees. FR emphasised that their national coding system provides a high degree of traceability and questioned the need for an international one. DE confirmed not seeing any need for an international coding system. IT supported the views of FR and DE.

The Commission stressed that there are differences in distribution of blood and tissues & cells. While tissues and cells move cross-border, this is generally not the case for blood and blood components. WHO will provide further written information.

6.5. EMA – Inspection and Control Measures

The European Medicine Agency (EMA) presented the `Application of Inspection and Control Measures to facilitate risk based inspection planning of sites registered in Plasma Master Files` to the group. The Dutch competent authority raised questions about the requirement of a maximum of two year inspection interval of mobile centres. There was need for clarification if this requirement should not apply to these centres. It was explained that while the two years inspection interval requirement in regard to blood establishments is enshrined in legislation, the situation of mobile centres is different.

Under the current legislation it is uncertain if these centres must also be inspected every 2 years or could be treated differently, for example according to risk (EMA). Respecting the two year requirement is difficult in practice due to the character of mobile centres. The French competent authority raised a question if the same should apply not only to mobile centres but also to mobile collection teams. It was explained that collection teams have to be inspected during regular inspections of blood establishments.

The German competent authority noted that risk-based inspections do not comply with the current national provisions in Germany. SE raised the issue if a risk-based model could also apply to mobile testing laboratories. EMA explained that they have not

considered a simple collection procedure, but rather the situation where a laboratory is under the control of a mobile centre. Otherwise ordinary control measures by testing laboratories are still expected.

Member States should send comments by the end of April to EMA.

6.6. Overview of the blood market (Creativ Ceutical)

The Commission informed the group that comments have been received and now they are being included. The Commission will report back on this topic during the next CA meeting.

7. ANY OTHER BUISNESS

7.1. Surplus blood: Record of traceability

The Greek competent authority explained that there is a need for reflection on the exchange of surplus blood between Member States. In order to facilitate this exchange, urgent situations and equivalence criteria should be further elaborated. It was clarified that during the next competent authorities meeting there will be a template for exchange agreements provided.

7.2. Advanced Medical Therapy Products

The UK competent authority is concerned that the Blood Directive is not included in the legislation on advanced-therapy medicinal products. The Commission will reflect this issue and react if necessary.

DOMINIK SCHNICHELS