EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718)

Meeting of the Competent Authorities on Blood and Blood Components

24 April 2015

Summary Report

PARTICIPATION:

All Member States except Luxembourg were present at the meeting of the competent authorities (CAs) on blood and blood components on the 24 April 2014. Norway and Turkey, as well as the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM – CoE), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the Consumers, Health, Agriculture and Food Executive Agency (Chafea) also attended the meeting.

Chairman: Mr D. SCHNICHELS (SANTE)

Commission: Mr S. VAN DER SPIEGEL, Ms D. FEHILY, Ms I. HOLMQUIST, Ms I. SISKA, Mr R. MCGEEHAN, Mr P. CATALANI, (SANTE)

1 CONFLICTS OF INTEREST

No conflicts of interest were declared.

2 ADOPTION OF THE AGENDA

The agenda was adopted without any changes.

3 REGULATORY MATTERS: POINTS FOR INFORMATION

3.1 Infringement proceedings

The Commission informed the group that the transposition check is now closed for all Member States. One infringement proceeding is, however, ongoing.

3.2 Report on the implementation of the EU Blood Directives (Article 26 of the Directive 2002/98/EC)

The Commission presented the key findings of the implementation report, including: competent authorities' responsibilities, accreditation/designation/authorisation/licensing of blood establishments, inspection and control measures, haemovigilance, import/export, donor screening and donor testing/pathogen inactivation. In its conclusions, the Commission explained that the legislation is applied at an acceptable level in the EU Member States and EEA countries, but there are still some gaps and challenges, in particular relating to authorisations, CA organisation and activities, borderline issues, national additional requirements on testing and deferral, and issues with vigilance systems and SARE reporting

IE highlighted that the scope of Directive 2002/98/EC to apply to the collection and testing of blood and blood components, 'whatever their intended purpose', was too broad. EMA also added that the definition of 'blood establishment' was problematic, in particular in relation to inspections and third country plasma sites. Member States supported the idea for common inspection and authorisation procedures for blood establishments.

Regarding haemovigilance, several Member States believe that there is underreporting of adverse reactions and events, in particular by hospital blood banks. The Commission also reported that some Member States had suggested the introduction of mandatory reporting of SAR in donors. Regarding import, DE emphasized that there is growing demand for plasma derivatives and continued demand for Anti-D which is not produced in Europe.

Some Member States reiterated their call for a revision of the legal framework. The Commission indicated that no discussions had taken place and that no decisions had been taken.

Member States supported the mapping of stricter/additional national measures by the Commission, adding that the mapping should take into account legally binding and recommended measures (evaluating whether they are in practice mandatory).

3.3 Report on the promotion of voluntary unpaid donations (Article 12.2 of Directive 2002/98/EC)

The Commission presented the key findings of the report on voluntary unpaid donation, including: legislative provisions for VUD, practices vis-à-vis donors, practices vis-à-vis collectors, ensuring sufficient supply of components and derivatives and the organisation of collection and supply. The findings indicate a strong support for VUD but a varying implementation of the practice within the Member States. In its conclusions, the Commission highlighted the need to both respect the VUD principle and ensure an adequate supply of blood, blood components and plasma derivatives. Some Member States suggested better defining the notion of compensation.

MT reported that donors are only accepted if they give helping others as the reason for donating. IE is currently working on an overarching policy and guidelines for VUD but this has proved difficult in the past. The Commission encouraged Member States to share any guidelines they may have within the group.

3.4 Court cases

The Commission explained that the preliminary ruling in case C-528/13 (Geoffrey Léger v Ministre des Affaires sociales, de la Santé et des Droits des femmes and Établissement français du sang) was expected on 29 April. The Commission agreed to inform Member States of any implications of the upcoming ruling on the implementation of the EU blood Directives and indicated its intention to send a questionnaire to Member States how they intend to implement the judgment.

4 PRESENTATION OF KEY INTERPRETATION ISSUES AND DISCUSSION

4.1 Deferral criteria for sexual risk behaviours

Several Member States gave updates of their practices regarding deferral of men who have sex with men (MSM) from donating blood.

NL explained that Sanquin is doing a study of MSM and blood transmissible infections and will report any findings back to the group. DE is currently reflecting on deferral criteria for MSM and is planning a revision of blood donor deferral criteria in mid to late 2016. PT has established a working group that is analysing data on MSM and blood donation that will report to their Parliament this year.

In 2012, SE changed their deferral criteria for sexual risk behaviour for blood donations intended for transfusion to one year. IT and RO explained having an individual risk assessment for every donor. In IT, this has not had a significant impact on HIV prevalence in the donor population. FR is currently reflecting on changing the legislation regarding sexual risk behaviours. IE and EL are also reflecting on deferral of MSM.

DK indicated that there is a clear link between MSM donation and HIV transmission and highlighted the risks of allowing this group to donate blood. CZ asked if the wording of the Directive on sexual risk behaviours could be changed. Many Member States highlighted the need for a well-designed donor questionnaire to ensure that donors are deferred appropriately.

'The group discussed the need to base deferral policies on epidemiological data and scientific research. EDQM agreed that the donor questionnaire is key for ensuring blood safety and will collect questionnaires used in the Member States as part of their study of sexual risk behaviours. EDQM will look at various issues related to MSM and blood donation, but explained that epidemiological situation and sexual practices vary between countries making general conclusions difficult. The role of donor questionnaires, self-exclusion practices, education of staff, donors and gay communities were emphasised. The Commission will circulate a short questionnaire to update their overview of deferral criteria for sexual risk behaviours in the EU.

The Commission explained that the wording of the Directive is general to allow Member States to establish deferral criteria based on the specific situation in their Member States.

4.2 Lymphocyte immunotherapy

The Commission explained that a note to the legal service is being prepared regarding the classification of LIT and promised to provide detailed feedback at the next CA meeting.

5 PRESENTATIONS OF PROJECTS, ACTIVITIES AND EU FUNDING

Member States agreed that the Patient Blood Management team could present issuance figures provided to them by the CAs at scientific conferences.

The Commission informed Member States that the Creativ Ceutical Report has now been published.

5.1 Joint action on blood and tissues and cells

The joint action will be co-ordinated by the Instituto Superiore di Sanita in Italy, which covers both the blood and tissues and cells competent authorities. The joint action should hopefully start in September.

5.2 Eurobarometer

The Commission presented the initial results of the Eurobarometer survey on blood and tissue and cell donation. The main conclusions were that Europeans are generally quite willing to donate and quote altruistic reasons for doing so. The majority of respondents felt that blood transfusion was safe but in some countries a large proportion of respondents answered 'don't know', which may suggest a lack of awareness. Respondents' main safety concerns were contracting a disease, complications or medical errors, which is reflected in their support for legislation on safety and quality.

5.3 Council of Europe

EDQM reported that there are two new resolutions by the Committee of Ministers on haemophilia therapy and immunodeficiency therapy. The 18th Edition of the Guide to the Preparation, Use and Quality Assurance of Blood Components will be published soon. The good practice guidelines will also be updated periodically in conjunction with GMP Annex 14 and the update of the guide.

Regarding the blood quality management system activities, a training course was organised at EDQM in April with 36 participants from 28 EU/Council of Europe members.

An update on the B-PTS and B-QM activities was also provided.

- Good practice guidelines for elements of the quality system

The Commission thanked the group for the comments provided on the draft GPG as developed by a joint working group with the Council of Europe's EDQM. The Commission's services informed the group that they are currently reflecting how best to adopt these guidelines taking into account the procedures which need to be followed and the objective to keep the guidelines aligned with the version to be published in the CoE Blood Guide.

5.4 WHO update

IT presented the WHO Executive Board decision on the donation and management of blood, blood components and medical products of human origin (MPHO). This decision requests that the WHO DG to "support the development of global consensus on guiding ethical principles for the donation and management of the mentioned medical products of human origin; good governance mechanisms; and common tools to ensure quality, safety and

traceability, as well as equitable access and availability, as applicable". It will be submitted to the 70th World Health Assembly.

5.5 EMA update

EMA give an update on inspections and inspection intervals (in particular risk based inspections) of plasma collection sites. Risk based inspections allow authorities to evaluate the activities of specific sites and tailor inspections and inspection intervals to these risks, inspecting sites with less activity and good compliance every 5 years and those with poor compliance every year.

The Commission explained that they are aware that inspection intervals are an issue for authorities. However, the Commission reminded the group that any inspection regimes which incorporate risk-based assessments would need to respect the requirements of Directive 2002/98/EC in terms of inspections intervals and the definition of the terms 'blood establishment' and 'inspection'.

6 SURVEILLANCE AND VIGILANCE: UPDATE ON INFECTIOUS DISEASES RISKS

6.1 ECDC update

ECDC presented information on the current outbreaks of Ebola, H5N1 and Mycobacterium chimaera. The threat to blood safety by the Ross River Virus infection was also presented. Ongoing ECDC activities include the prioritisation of bacterial infections with relevance for SoHO, an assessment of donor registration and risk assessments for chikungunya, Chagas disease and leishmaniasis.

6.2 Alerts (oral updates)

6.2.1 Hepatitis E

DE has seen an increase in HEV cases over the past fifteen years (in 2001 there were 31 cases and in 2014 670 cases). DE explained that they do not think there is a need for screening of components but testing of components for immunocompromised patients should be considered. FR explained that in the last three years there were 21 cases of HEV transmission (about 10% of all transfusion transmitted infections). The patients were mainly immunocompromised. Five recovered without treatment and 11 were treated over several months.

EL reported that they have had no cases of transmission of HEV. A number of Member States reported that transmission of HEV is usually food related and morbidity is low. The main risk is to immunocompromised patients.

The Commission agreed to survey Member States of their current and future plans for HEV screening and to come back to this point in the next meeting.

6.2.2 Follow-up on reported cases of chikungunya

FR reported that the chikungunya epidemic has ended in Martinique, Guadelaupe and French Polynesia. There is still some transmission in Saint Martin and Saint Barthelemy.

Chikungunya is still active in French Guiana. There is still a 28 day deferral after return to France from these regions.

6.2.3 Follow-up on reported cases of WNV (EL, IT)

EL reported that there is one case per 11,289 units. The public health measures will be the same as for previous years. EL also reported that there is an association between outcome and ABO, D/Rh, Lewis blood groups and HLA class. There has been one reported case of transmission of WNV through blood but there may be more asymptomatic cases.

IT reported that their new approach to prevention through vector surveillance is working well. The density of mosquitoes over a week period is evaluated and on this basis NAT testing is introduced. IT also reported that they have detected 49 affected blood donors but no transmissions to patients through blood have been reported. There has been one case of transmission through organs.

6.2.4 Follow up on reported cases of dengue

FR reported that the situation in the overseas departments is under control but precautionary measures are still in place. There are some reported cases in the south of France. PT reported that there have been no further cases of dengue in Madeira.

6.2.5 Malaria (EL)

EL reported that there were three locally acquired cases in 2013 but no cases in 2014. There have been no reports of transfusion transmitted malaria to the the EL haemovigilance centre.

6.2.6 Other

Member States had no additional epidemiological alerts to present.

7 SERIOUS ADVERSE EVENTS AND REACTIONS (SARE) AND ALERTS

7.1 RAB alerts

The Commission reported that there were no new alerts on RAB in 2015 and encouraged Member States to complete the evaluation and close any open alerts from 2014.

7.2 SARE reporting exercise 2015

The Commission will launch the 2015 SARE exercise in June with a deadline of the end of July. There are no major changes to the template besides the addition of a contact email field to allow us to easily contact the individual/authority responsible for SARE reporting.

8 ANY OTHER BUSINESS

8.1 Surplus blood

NL presented a list of criteria that should be considered when developing a format to exchange blood. EL will circulate a final proposal for the format to exchange surplus blood.

8.2 FDA visit

The Commission gave a short overview of the activities of CBER (Centre for Biologics Evaluation and Research) at the FDA.

This presentation covered the US set-up including the organisation of CBER, the US legal framework, registration of Blood Establishments in the US and licensure of blood products. Additional information was given on plans to change deferral criteria for MSM, SARE reporting and risk assessments. A final point of interest related to the evaluation of novel blood products and related techniques.